

IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE
TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

FILED
2012 OCT 8 AM 10:00
RICHARD R. ROOKER, CLERK

STATE OF TENNESSEE,)
ex rel. ROBERT E. COOPER, JR.,)
ATTORNEY GENERAL and REPORTER,)

Plaintiff,)

v.)

JURY DEMAND

HRC MEDICAL CENTERS, INC., a domestic)
corporation, *formerly known as* HAIR)
RESTORATION CENTERS OF TENNESSEE,)
INC., HRC MANAGEMENT MIDWEST, LLC,)
a foreign limited liability company,)
DAN E. HALE, D.O., *individually and as an*)
officer, and DON HALE, *individually and as an*)
officer,)

Defendants.)

Case No. 12 C 4047

COMPLAINT
FOR TEMPORARY AND PERMANENT INJUNCTION, JUDICIAL CORPORATE
DISSOLUTION, AND OTHER RELIEF

1. This civil law enforcement action is brought in the name of the State of Tennessee, in its sovereign capacity, by and through Robert E. Cooper, Jr., Attorney General and Reporter, pursuant to Tenn. Code Ann. § 47-18-108 of the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* ("TCPA") to protect consumers and the integrity of the commercial marketplace in Tennessee. Further, pursuant to Tenn. Code Ann. § 48-24-301, the State seeks to judicially dissolve Defendant HRC Medical Centers, Inc. ("Defendant HRC Medical") for transacting business in a persistently fraudulent manner.

2. Gary Cordell, the Director of the Division of Consumer Affairs of the Department of Commerce and Insurance, has requested that the State of Tennessee, through the Attorney General, commence a civil law enforcement proceeding against the above-named Defendants, HRC Medical Centers, Inc., HRC Management Midwest, LLC, Dan E. Hale, D.O., individually and as an officer, and Don Hale, individually and as an officer, for violations of the TCPA. The Director and the Attorney General have reason to believe that Defendants have violated the TCPA by, among other things, saturating the commercial marketplace in Tennessee with false and misleading statements and material omissions about the safety, efficacy, benefits, side effects, and risks of Defendant HRC Medical's alternative regimen of "bio-identical" hormone replacement therapy (hereinafter "BHRT") and its purported superiority over traditional commercial hormone replacement therapy, which consists of conjugated equine estrogens and/or progestins or other forms of estrogen and progesterone (hereinafter "HRT" or "traditional hormone replacement therapy regimens").

3. Pursuant to Tenn. Code Ann. § 47-18-108(a)(2), the Director of the Division of Consumer Affairs has determined that the purposes of the TCPA will be substantially impaired by a delay in instituting legal proceedings and has not provided Defendants with 10 days' notice of the State's intention to initiate legal proceedings against them.

4. As set forth below, the State's civil law enforcement action under the TCPA concerns Defendants' advertising, sales, and contractual practices for Defendants' purportedly unique alternative regimen of BHRT for both men and women.

5. This Complaint is being filed concurrently with an *Ex Parte* Motion for a Statutory Temporary Restraining Order, a Motion for an Order Appointing a *Pendente Lite* Receiver Over HRC Medical Centers, Inc., a Motion for a Statutory Temporary Injunction, supporting exhibits, and

a Memorandum in Support. An annotated version of this Complaint that provides footnotes to factual assertions made in this Complaint is attached to the Motion for a Statutory Temporary Restraining Order as Exhibit 1.

GENERAL FACTUAL ALLEGATIONS

6. Defendants advertise, sell, and administer a purportedly unique cocktail of “bio-identical” hormones that are extracted from sweet potatoes or soybeans, converted into pellet form, and then inserted beneath the skin of the consumer based on a hormone regimen program that was created, implemented, and overseen by an unlicensed medical assistant with no formal training, but with full approval from Defendants Dan Hale and Don Hale.

7. Defendants have structured the BHRT component of their business using a highly aggressive sales model—especially for a business in the medical field. Under Defendants’ sales model, appointments for consumers who call in to set up “free” consultations are prioritized based on prior sales success. The most successful sales consultant is given first priority. Notably, most of Defendant HRC Medical’s sales consultants, who have no or very little hormone-related training, have their daily sales conversion ratios monitored and are paid on a *100% commission basis*—meaning that the sales consultant does not get paid unless the consumer purchases BHRT. When the consumer arrives at the HRC office for the consultation, the consumer is asked to fill out a “symptom” questionnaire that features broadly-applicable purported symptoms of hormone deficiency, like “tiredness,” “poor focus,” and “memory lapses.” For the vast majority of consumers, Defendants have determined that they are candidates for BHRT even if they only check one of the broadly applicable purported symptoms.

8. Unlike traditional hormone replacement therapy regimens, which are provided to menopausal women for short-term use, Defendants market their BHRT to practically all age ranges for long-term or perpetual use, which dramatically increases risk factors, safety concerns, and side effects. Defendants' BHRT cocktail for women includes estrogen and, *unlike traditional hormone replacement therapy regimens*, also includes mega-doses of testosterone in amounts intended to reach levels typically found in men—*amounts between three and four times the upper range of testosterone found in most normal women*—unbeknownst to their female consumers. For men, the BHRT cocktail includes mega-doses of testosterone that are intended to reach levels up to *two to three times* the levels found in most normal men—unbeknownst to their male consumers.

9. The hormone pellets for the BHRT cocktail are not produced by Defendant HRC Medical, but rather by MasterPharm, Inc., a compounding pharmacy with which Defendant Don Hale has executed a long term contract and in which he has invested. As known to Defendants, this compounding pharmacy has had quality control problems with the compression of the pellets given to consumers in Tennessee—a problem in and of itself that makes the release of the hormones in Defendants' BHRT wholly unpredictable and potentially dangerous.

10. The advertising component of Defendants' sales model is equally troublesome. Defendants assert that their BHRT is completely safe and virtually risk and side effect free largely because the ingredients used in the therapy purportedly come from natural sources and are purportedly identical to the hormones that the body produces. Defendants have gone so far as to assert not only that their therapy is perfectly safe, but, on multiple occasions, *that it is unsafe not to go through with the therapy*. These sweeping safety, risk, and side-effect claims for Defendant HRC Medical's BHRT are false, deceptive, and/or not adequately substantiated.

11. Defendants' misrepresentations asserting absolute safety, limited or no risk, and no or minimal side effects in advertisements were known by Defendants to be false, deceptive, and/or unsubstantiated based on numerous consumer complaints. These misrepresentations were also widely discussed within Defendant HRC Medical including through internal emails and at several meetings that Defendants Don and Dan Hale led and attended.

12. Defendants have also falsely, deceptively, and/or without adequate substantiation claimed that their BHRT can increase a consumer's lifespan and can act as a veritable wellness cure-all—acting to prevent, treat, or cure a large number of diseases and conditions associated with aging or reverse the effects of aging itself. Moreover, Defendants have claimed—falsely, deceptively, and/or without adequate substantiation—that their BHRT involves no cancer risk, protects against cancer, has no or minimal side effects, provides cardiovascular benefits, reduces cholesterol, increases head hair growth, increases head hair thickness, causes weight loss, helps control weight, and prevents, treats, or cures heart disease, high cholesterol levels, Alzheimer's Disease, memory loss generally, diabetes, Attention Deficit Hyperactivity Disorder, depression, fibromyalgia, arthritis, Restless Leg Syndrome, hair loss, and a host of other diseases and conditions commonly associated with aging.

13. In addition to Defendants' false, deceptive, and/or unsubstantiated express claims, Defendants, in advertisements for their BHRT, have either failed to clearly and conspicuously disclose or purposefully understated potential serious side effects from their alternative BHRT regimen, including increased risks of endometrial cancer, tissue edema, changes in lipids, and other serious health risks, including possible increased risks of breast cancer, as well as other side effects that may significantly impair a consumer's quality of life such as long-term or permanent hair loss on

the top of one's head, voice deepening, weight gain, significant hair growth in undesired areas of the body like the face, buttocks, and chest for women, increased anxiety, paranoia, psychosis, infertility, and long-term or permanent disfigurement of the consumer's genitals and other body parts.

14. The sweeping marketing claims for alternative hormone replacement regimens, like those made by Defendants for their BHRT, have no credible scientific basis and have been disputed by the United States Food and Drug Administration ("FDA"), the American Medical Association, the Endocrine Society, the American Congress of Obstetricians and Gynecologists, the North American Menopause Society, the American Association of Clinical Endocrinologists, the American Cancer Society, a representative of the Mayo Clinic, and other highly-reputable groups and individuals within the medical community.

15. The State asserts that Defendants have violated the TCPA in the following ways:

- by making false, deceptive, and/or unsubstantiated claims about the safety, benefits, efficacy, risks, and side effects of Defendant HRC Medical's BHRT;
- by making false, deceptive, and/or unsubstantiated superiority claims about the safety, benefits, efficacy, risks, and side effects of Defendant HRC Medical's BHRT compared with traditional hormone replacement therapy regimens;
- by claiming falsely, deceptively, and/or without adequate substantiation that Defendant HRC Medical's BHRT restores a consumer's hormone levels to the levels he or she had in his or her twenties or thirties;
- by failing to clearly and conspicuously disclose or understating serious side effects or health risks associated with Defendant HRC Medical's BHRT;

- by misrepresenting the expertise of Defendant HRC Medical's former chief spokesperson, Dr. Dan Hale, and other individuals at Defendant HRC Medical with respect to hormones;
- by falsely stating that the compounding pharmacy used by Defendant HRC Medical to supply its pellets has been approved by the FDA;
- by deceptively claiming that the compounding pharmacy used by Defendant HRC Medical for its BHRT adheres to high quality control measures and produces optimized, time-released pellets;
- by using fabricated quotes of purported findings of medical studies in promotional materials;
- by misrepresenting the amount of support for its health claims,
- by misrepresenting the number of satisfied consumers;
- by repeatedly holding out officers, directors, employees and others as consumers of Defendant HRC Medical's BHRT in testimonials without clearly and conspicuously disclosing their material connections to Defendant HRC Medical or its principals;
- by using consumer testimonials without clearly and conspicuously disclosing side effects the consumer experienced;
- by using consumer testimonials without disclosing benefits the consumer received for providing his or her testimonial; and
- by requiring a consumer to sign a non-refundable contract for thousands of dollars for *future* treatments of BHRT without knowing how a consumer will *initially* respond to the BHRT, without knowing whether a future hormone pellet implant would be

appropriate *at the time given*, and before, in most cases, a consumer has even had his or her blood taken or met with anyone remotely resembling a medical professional.

16. These advertising and contractual acts or practices, both individually and cumulatively, have endangered the health of consumers in Tennessee without the consumers' knowledge, have significantly impaired the quality of life for an untold number of Tennessee consumers, and have caused widespread economic loss.

JURISDICTION AND VENUE

17. As a court of general jurisdiction, the circuit court is authorized to hear this matter, based on the TCPA cause of action asserted, the amount at issue, and the relief sought.

18. Venue is proper in Davidson County pursuant to the TCPA's specific state enforcement venue provision, Tenn. Code Ann. § 47-18-108(a)(3), because it is a county where the alleged violations took place and is also the county in which Defendants conduct, transact, or have transacted business. Because this action is also one to judicially dissolve Defendant HRC Medical, venue is also proper in Davidson County under Tenn. Code Ann. § 48-24-302(a).

19. Defendant HRC Medical Centers, Inc. operates an office at 301 14th Avenue North, Nashville, TN 37203. At the office, Defendant HRC Medical meets with current and prospective consumers of its BHRT, enters into contracts with consumers for its BHRT, records advertisements, and administers the BHRT at issue in this Complaint.

20. Defendant HRC Medical previously transacted and continues to transact business at 301 14th Avenue North, Nashville, TN 37203 in Davidson County, a property that Defendants Don Hale and Dan Hale own. Prior to moving to its address on 14th Avenue, Defendant HRC Medical

also transacted business in Davidson County at 1916 Patterson Street, Suite 500, Nashville, TN 37203.

21. Defendant HRC Medical's Nashville office has provided its BHRT to more consumers in Tennessee than any other location in Tennessee.

22. Prior to April 1, 2012, Defendant HRC Medical listed its principal place of business as 301 14th Avenue North, Nashville, TN 37203 on its corporate filings with the Tennessee Secretary of State and listed the same address as the contact for Defendant HRC Medical's registered agent.

23. Defendant Dan Hale, Defendant Don Hale, and other employees, officers, or agents of Defendant HRC Medical have also routinely appeared through media outlets in Davidson County for the purpose of advertising Defendant HRC Medical's BHRT.

24. Defendant HRC Medical has placed more advertisements for its BHRT with media outlets based in Davidson County than any other location in Tennessee.

SPECIFIC FACTUAL ALLEGATIONS

PLAINTIFF

25. Plaintiff, State of Tennessee *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, is charged with enforcing the TCPA. Pursuant to Tenn. Code Ann. § 47-18-108, actions for violations of the TCPA may be brought by the Attorney General with approval from the Division of Consumer Affairs in courts of competent jurisdiction to restrain violations, to secure equitable and other relief, and to otherwise enforce the provisions of the TCPA.

DEFENDANTS

26. Defendant HRC Medical is a domestic corporation. In its most recent filing with the Tennessee Secretary of State, Defendant HRC Medical lists its principal place of business as 405 Duke Drive, Suite 240, Franklin, Tennessee 37067. In addition to the Nashville office, Defendant HRC Medical owns and operates a location in Knoxville. HRC Medical Centers-branded clinics are also located in Memphis, Alabama, Arizona, Colorado, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Michigan, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Oklahoma, South Carolina, Texas, and Virginia through joint ventures or other corporate structures that function similar to franchises (hereinafter “franchise” or “franchisee” to refer to other corporate partners).

27. Defendant HRC Medical, which claims to be the largest provider of BHRT in the country, has also made other treatment offerings to consumers including a facial peel laser program, a non-FDA approved weight loss program with human chorionic gonadotropin (“HCG”), a purported water-based alternative to liposuction, and hair restoration therapy. Defendant HRC Medical’s BHRT, however, is the most heavily advertised offering and has been purchased more often than any other offering.

28. Defendant HRC Management Midwest, LLC (“Defendant HRC Management Midwest”) is a limited liability company formed in Delaware that currently owns and operates the Memphis office of HRC Medical. Defendant HRC Management Midwest also owns and operates other HRC Medical offices including ones in Overland Park, Kansas and Omaha, Nebraska. Throughout its operation of the Memphis office, Defendant HRC Management Midwest has used advertising, promotional, and contractual materials provided by Defendant HRC Medical and has directed consumers to the websites owned by Defendant HRC Medical.

29. On February 17, 2012, Defendant HRC Management Midwest registered as a limited liability company with the Delaware Department of State. Later, on April 23, 2012, Defendant HRC Management Midwest, filed an Application for Certificate of Authority for a Limited Liability Company with the Tennessee Secretary of State, which was signed by Defendant Dan Hale's daughter, Dana R. Helton, as a member. Dana Helton has responded to numerous complaints from consumers concerning their BHRT purchases, including those who referenced serious side effects, on behalf of Defendant HRC Medical. Since at least March 1, 2012, Defendant HRC Management Midwest has owned and operated the Memphis office.

30. Defendant Dan Hale is a doctor of osteopathy who currently resides at 255 Rock Point Drive, Vonore, Tennessee 37885-2068.

31. Defendant Dan Hale was one of the original incorporators of what is currently Defendant HRC Medical and has served as president, secretary, and vice president of Defendant HRC Medical.

32. Defendant Dan Hale's training for hormone replacement therapy primarily came from a single two-day conference and from Trina Lonning, an unlicensed individual with a medical assistant's certificate from the Nashville Court Reporting Academy who was hired by Defendant Dan Hale with Defendant Dan Hale's knowledge and approval to set up Defendant HRC Medical's entire BHRT program. Defendant Dan Hale's first exposure to hormone replacement therapy happened when Ms. Lonning accompanied him to this *two-day* conference sponsored by SottoPelle, another BHRT provider based in Arizona. Even within these two-day conferences, limited time is devoted to substantive training on hormone replacement therapy. A representative agenda for a

similar seminar that Ms. Lonning attended on behalf of Defendant HRC Medical, which devoted one and a half hours to “Maximizing Profit From the Beginning,” is excerpted below in Figure 1:

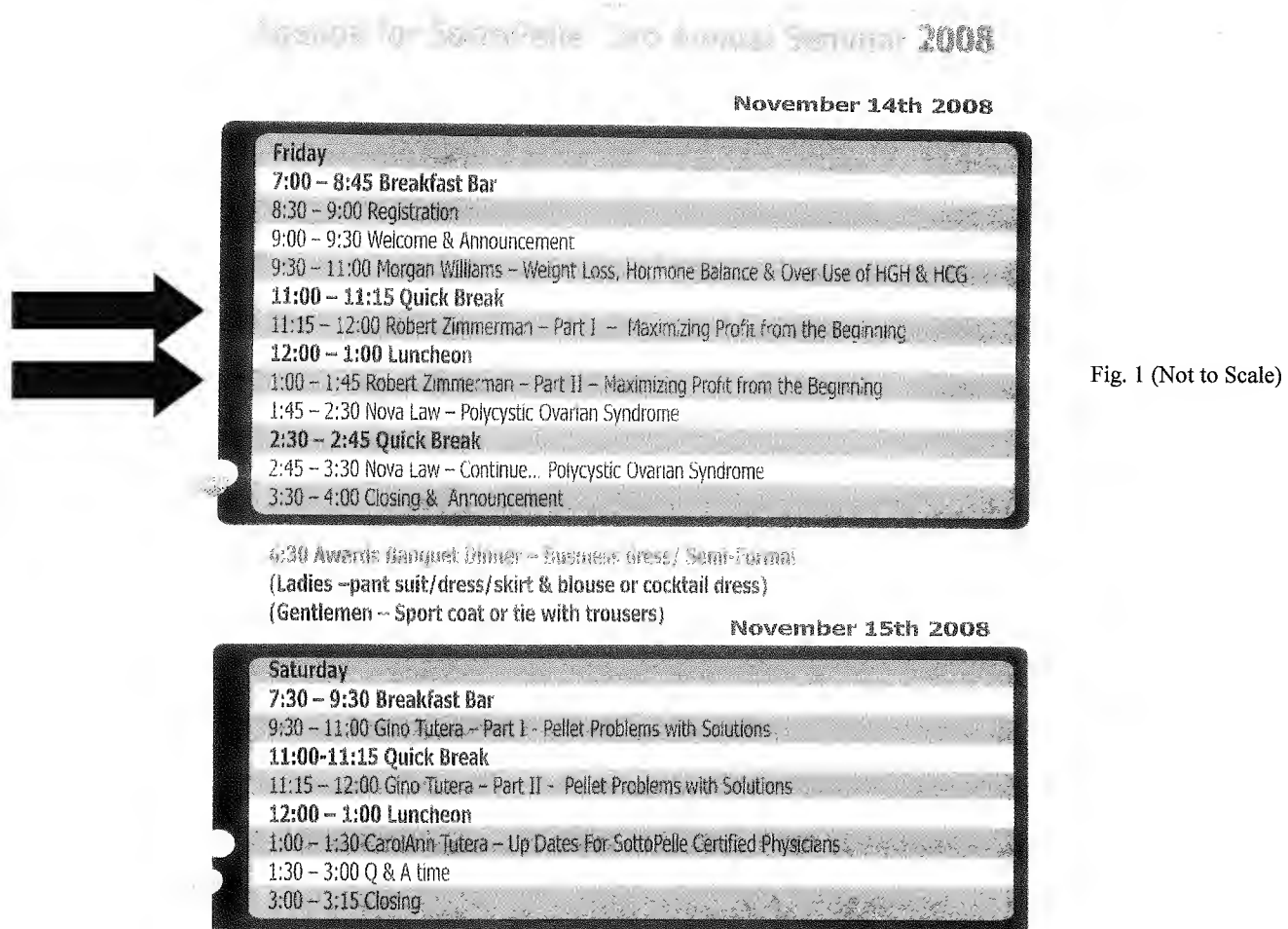


Fig. 1 (Not to Scale)

33. At the November 2008 SottoPelle conference in Las Vegas, excerpted above as Figure 1, Defendant Dan Hale placed an order for over \$20,000 worth of hormone pellets.

34. Since graduating as an osteopath in 1974, Defendant Dan Hale has spent the overwhelming majority of his professional life in fields unrelated to hormone replacement. Defendant Dan Hale has been a family practitioner, an emergency room doctor, a pain clinic doctor, not practicing medicine at all, a doctor performing mostly non-FDA approved cosmetic therapies, or a hair transplant doctor.

35. Defendant Dan Hale has no specialty board certification recognized by the Tennessee Department of Health. His limited training with hormone replacement therapy comes from a certification he received in 2007 from Cenegenics, a multi-level marketing company which teaches and sells "age management" techniques, and from the two-day SottoPelle conferences referenced above.

36. Advertisements for Defendant HRC Medical's BHRT have emphasized the central role that Defendant Dan Hale has played in the development of Defendant HRC Medical's BHRT. For example, in one commercial, Nashville television personality Charlie Chase stated the following on behalf of Defendant HRC Medical about Defendant Dan Hale's experience concerning hormone replacement therapy:

CHARLIE CHASE: *Under the direction of one of the nation's leaders in hormone replacement and my friend, Dr. Dan Hale*, HRC Medical has now made life better for more than 30,000 people all across the country. (emphasis added)

37. Defendant Dan Hale has frequently spoken about Defendant HRC Medical's BHRT in advertisements broadcast on television stations in Tennessee, on the Internet, and in other media, including speaking about its purported efficacy, benefits, lack of risks, lack of side effects, and safety, and its purported superiority compared to traditional hormone replacement therapy regimens.

38. Defendant Dan Hale has also told other employees or contractors of Defendant HRC Medical or its franchisees what to say about Defendant HRC Medical's BHRT.

39. Defendant Dan Hale has had direct knowledge about the side effects and health risks of BHRT that are not disclosed in and that contradict his statements and those made by others about the purported efficacy, benefits, lack of risks, lack of side effects, and safety of Defendant HRC Medical's BHRT and its purported superiority to traditional hormone replacement therapy regimens.

40. In group meetings that Defendant Dan Hale attended, in documents that Defendant Dan Hale reviewed, and through in-person meetings, consumers or employees of Defendant HRC Medical told Defendant Dan Hale directly about side effects or serious health conditions that consumers experienced, which were not previously disclosed, clearly or conspicuously or otherwise, by Defendant HRC Medical in advertisements for its BHRT.

41. Through conversations and communication with employees of Defendant HRC Medical, Defendant Dan Hale also had knowledge about significant quality-control problems at the compounding pharmacy that Defendant HRC Medical was using (and continues to use) to provide the pellets for its BHRT, including with the consistency of pellet compression—a problem that makes the release of hormones unpredictable, risky, and potentially dangerous.

42. Defendant Dan Hale also received notice of the serious side effects associated with Defendant HRC Medical's BHRT in an action by the North Carolina Medical Board in 2011 that denied Defendant Dan Hale's application for reinstatement of his medical license.

43. Defendant Dan Hale actively participated in, had knowledge of, or had control of the conduct, as set forth above and below. Defendant Dan Hale acted without good faith as set forth above and below.

44. Defendant Don Hale, who is Defendant Dan Hale's brother and a former boxing promoter, is the President and Chief Executive Officer of Defendant HRC Medical, Inc. and is the current registered agent of Defendant HRC Medical.

45. After seeing BHRT as a potential profit source for Defendant HRC Medical, Defendant Don Hale sought out Trina Lonning, an unlicensed individual with a medical assistant's certificate from the Nashville Court Reporting Academy who worked at another BHRT provider.

Defendant Don Hale hired Ms. Lonning to set up Defendant HRC Medical's entire BHRT program, teach Defendant Dan Hale about BHRT, sell BHRT to consumers, establish dosing for Defendant HRC Medical's BHRT, conduct blood hormone draws for Defendant HRC Medical's BHRT, and administer the pellet injections of the BHRT itself. In front of other employees of Defendant HRC Medical, Defendant Don Hale openly praised Trina Lonning for setting up and bringing him the hormone replacement therapy business.

46. Defendant Don Hale has approved advertisements for Defendant HRC Medical's BHRT and authorized discounts for the therapy for consumers who appeared in advertisements for Defendant HRC Medical's BHRT.

47. Defendant Don Hale has spoken about Defendant HRC Medical's BHRT in advertisements, including about its purported efficacy, benefits, lack of risks, lack of side effects, and safety, and its superiority to traditional hormone replacement therapy regimens.

48. In meetings that Defendant Don Hale attended, in conversations that Don Hale had, and in correspondence that Defendant Don Hale received and acknowledged, employees of Defendant HRC Medical told Defendant Don Hale directly about safety concerns, risks, and side effects that consumers experienced, which were not previously disclosed, clearly and conspicuously or otherwise, by Defendant HRC Medical in advertisements for its BHRT.

49. Defendant Don Hale has had direct knowledge about the side effects and health risks of BHRT that are not disclosed in and that contradict his statements and those made by others about the purported efficacy and benefits of Defendant HRC Medical's BHRT and its purported superiority to traditional hormone replacement therapy regimens. As one example, Defendant Don Hale directly told Andrea Bernard, Defendant HRC Medical's most successful sales consultant, when her sales

numbers started to decline after she began telling consumers that they were not candidates for BHRT and started making health risk and side effect disclosures, not to talk so much, not to sound so “medical” and “clinical,” and specifically not to mention the risk of cancer and infertility for fear of scaring off potential consumers.

50. Defendant Don Hale has developed Defendant HRC Medical’s “no refund” policy, and has implemented a system in which only he and his wife, Dixie, could authorize refunds. In practice, Defendant Don Hale and his wife have denied refunds to consumers who complained about side effects associated with Defendant HRC Medical’s BHRT and those who were diagnosed with cancer while taking the therapy. During this process, Defendant Don Hale was notified of side effects and serious health conditions that consumers of Defendant HRC Medical’s BHRT experienced.

51. Additionally, after sending samples from Solutions Pharmacy to MasterPharm, a compounding pharmacy that had not previously sold hormone pellets, executing a lifetime contract, and investing in the company, Defendant Don Hale changed Defendant HRC Medical’s compounding pharmacy supplier of its BHRT pellets from Solutions Pharmacy to MasterPharm.

52. Through conversations and communication with employees of Defendant HRC Medical, including Trina Lonning, Defendant Don Hale also had knowledge about significant quality-control problems at the compounding pharmacy that Defendant HRC Medical has used to provide the pellets for its BHRT, including with the consistency of pellet compression.

53. Defendant Don Hale has made hiring and firing decisions for Defendant HRC Medical, including for its sales consultants who provide sales pitches for Defendant HRC Medical’s BHRT.

54. Defendant Don Hale placed Defendant HRC Medical's top sales consultants for its BHRT, Amanda Garrett and Andrea Bernard, on a *100% sales commission compensation structure*. Under the structure, Ms. Garrett and Ms. Bernard *did not get paid unless they closed a sale*.

55. Defendant Don Hale has regularly reviewed *daily* sales conversion ratios reflecting the number of sales made for BHRT compared with the total number of appointments and indicated that sales consultants would be terminated if their sales conversion ratios did not improve.

56. In addition, as shown below in Figures 2-6, many of the advertisements used by Defendant HRC Medical were recorded in Defendant Don Hale's office with his knowledge, approval, and sometimes in his presence.

Fig. 2
(Not to
Scale)

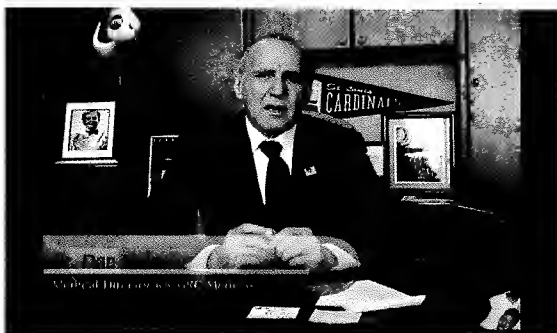


Fig. 3
(Not to
Scale)



Fig. 4
(Not to
Scale)



Fig. 5
(Not to
Scale)

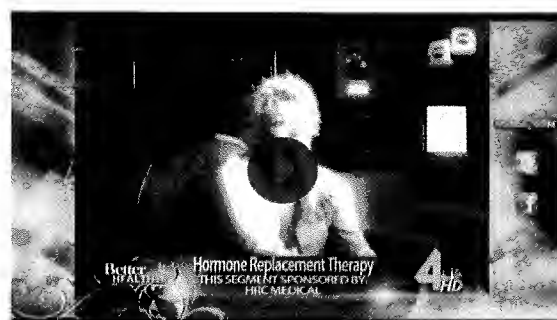




Fig. 6
(Not to
Scale)

57. In addition, Defendant Don Hale appeared at meetings of an Advisory Task Force created by the Tennessee Department of Health, which, among other things, discussed unsubstantiated benefit, safety, and superiority claims made by BHRT providers including Defendant HRC Medical.

58. Defendant Don Hale actively participated in, had knowledge of, or had control of the conduct, as set forth above and below. Defendant Don Hale acted without good faith as set forth above and below.

BACKGROUND OF HRC MEDICAL CENTERS, INC.

59. On August 16, 2004, Defendant Dan Hale, his wife Bonnie, and another individual incorporated Defendant HRC Medical in Tennessee under the name "Hair Restoration Centers of Tennessee, Inc."

60. Under the original corporate filing in 2004, Defendant Dan Hale was listed as the Secretary/Vice President.

61. As originally designed, Defendant HRC Medical was supposed to provide hair restoration services. At the time, the abbreviation "HRC" was used to mean "hair restoration centers."

62. On its 2005, 2006, and 2007 Corporation Annual Reports filed with the Tennessee Secretary of State, Defendant HRC Medical listed Defendant Dan Hale as President and Defendant Don Hale as Secretary.

63. During this time, Defendant HRC Medical also began providing cosmetic procedures, such as a purported water-based liposuction alternative—an offering that Defendant HRC Medical's sales consultants have described as being expensive, extremely painful, ineffective, and "the biggest joke there was."

64. Around this time, Defendant Don Hale met with Trina Lonning, an individual who worked at New Life Physicians, another BHRT provider, to discuss the possibility of setting up a hormone replacement therapy practice at Defendant HRC Medical. After meeting with Ms. Lonning, Defendant Dan Hale traveled to a conference sponsored by representatives of SottoPelle, an Arizona-based BHRT provider. When Defendant Dan Hale returned from the conference, Defendant HRC Medical added its alternative regimen of BHRT to its consumer offerings. Defendant Don Hale, with Defendant Dan Hale's knowledge and approval, asked Ms. Lonning, an unlicensed medical assistant, to create, implement, and oversee Defendant HRC Medical's BHRT program.

65. On its 2008 Corporation Annual Report filed with the Tennessee Secretary of State, Defendant HRC Medical listed Defendant Don Hale as President and Defendant Dan Hale as Secretary.

66. Prior to 2009, Defendant HRC Medical conducted business under the names "HRC Med Spa" and "Health Restoration Centers."

67. In 2009, HRC Medical officially changed its name on its corporate filings with the Tennessee Secretary of State from Hair Restoration Centers of Tennessee, Inc., to HRC Medical Centers, Inc.

68. On its 2009 Corporation Annual Report filed with the Tennessee Secretary of State, Defendant HRC Medical listed Defendant Dan Hale as President and Defendant Don Hale as Secretary.

69. On its 2011 Corporation Annual Report, the company changed its registered agent from Dixie Hale to Defendant Don Hale.

70. On March 29, 2011, Defendant HRC officially registered the service mark “Amor Vie” with the United States Patent and Trademark Office for its BHRT therapy. The Amor Vie service mark has registration number 3937287 and has been used since June 28, 2010. In the translations component of the service mark registration, Defendant HRC Medical stated, “The English translation of ‘AMORE [sic] VIE’ is ‘LOVE LIFE,’” which refers to the purported libido-enhancing benefit of the testosterone component of its BHRT.

BACKGROUND ON HORMONES

71. For most women, Defendant HRC Medical’s BHRT consists of varying combinations of three forms of hormones: estrogen, progesterone, and mega-doses of testosterone. For men, Defendant HRC Medical’s BHRT contains mega-doses of testosterone.

72. Hormones are substances produced by the human body that control how certain organs function. Hormones circulate throughout the human body to coordinate a wide variety of complex processes including fertility and growth. Hormones are secreted directly into the blood by the glands that create and store them to regulate metabolic processes throughout the body (*e.g.*

insulin) or in specific target organs (e.g. estrogen). The hormones bind with the receptors in cells, which creates a response in the cells or tissues. While all cells and tissues are exposed to hormones circulating in the bloodstream, only those cells possessing specific receptors will exhibit a biological response to that hormone.

73. The human body responds to sex hormones including estrogen, progesterone, and testosterone in very complicated ways that, in some instances, are not fully understood by medical science—*especially when given in combination. Some of the effects that a given sex hormone may have in isolation may be amplified or mitigated by another hormone.*

74. In both men and women, blood hormone levels can vary even within a given day.

75. Estrogen is a general term to describe a class of female sex hormones, which are primarily seen in the body in the form of estradiol, estrone, and estriol. The ovary produces estradiol, which is metabolized into another estrogen called estrone. Estriol is another form of estrogen metabolized from estradiol, which is weaker than the other two but still active.

76. Estrogen, including estradiol, in sufficient doses, may increase a woman's risk of developing endometrial cancer (cancer of the uterine lining), hyperplasia (abnormal cell growth), and other conditions.

77. Progesterone is a female sex hormone produced by the ovaries following ovulation, which helps prepare the lining of the uterus to receive an egg if it becomes fertilized by sperm. If fertilization does not take place, progesterone levels drop and menstrual bleeding begins.

78. Progesterone, in sufficient doses, reduces the risk of endometrial cancer associated with estrogen and is most often prescribed in combination with estrogen to women who still have their uteri. In addition to lessening the beneficial effects of estrogen on a number of tissues,

progesterone is known to carry its own risks, such as a possible risk of breast cancer. As a result, any therapeutic benefit of progesterone is generally outweighed by potential risks for women who no longer have their uteri.

79. There are several commercial progesterone products on the market. Progestin is the name for a type of synthetic progesterone, which is most commonly seen as medroxyprogesterone acetate ("MPA"). Some progesterone preparations consist of micronized progesterone meaning that the particle size of the progesterone compound is reduced.

80. Testosterone is known mainly as a male sex hormone but is also found in much smaller amounts in women. In men, testosterone plays an integral role in the development of male reproductive tissues found in the testicles, prostate, and penis. Testosterone also promotes secondary sex traits such as hair growth.

81. In women, testosterone is produced in much smaller amounts in the ovaries. In women, the enzyme aromatase converts testosterone into estrogen with the lower amounts of testosterone that are naturally produced by the body. This conversion can cause the use of supplemental testosterone to create side effects associated with excessive levels of estrogen. Supplemental testosterone, in sufficient levels, that is not converted to estrogen by the enzyme aromatase, may create excessive levels of testosterone in the female body.

82. Testosterone increases the number of red blood cells circulating in the body for both men and women. The main function of red blood cells is to carry oxygen in the blood to various cells in the body. The higher number of red blood cells allows oxygen to get to cells faster and may reduce the feeling of fatigue during and after a difficult workout. This effect is why some

professional athletes have sought to “dope” their blood using high doses of testosterone or various derivatives or analogs.

83. However, supplemental testosterone acts as an anabolic steroid in both men and women and is associated with a number of side effects. In both men and women, potential adverse effects from excessive levels of testosterone may include lowering of the voice, hair loss on the head, hair growth on other parts of the body including the face, chest, and buttocks, tissue edema (observable swelling from fluid accumulation in body tissues), changes in lipids, and psychological changes including anger or aggressive behavior.

84. Defendant HRC Medical has only recently started to reference, albeit inconspicuously and incompletely, that its BHRT may increase an individual’s hematocrit and hemoglobin levels. Hemoglobin is the protein contained in red blood cells that is responsible for the delivery of oxygen to the tissues. Hematocrit measures the volume of red blood cells compared to the total blood volume (red blood cells and plasma). High hematocrit levels for a sufficient duration increases an individual’s risk of developing a blood clot, stroke, or other cardiovascular problems, which is not disclosed by Defendant HRC Medical. These risks are even more pronounced in individuals with already high hematocrit level or those who have a red blood cell disorder.

85. In the areas of new hair growth, testosterone permanently causes the creation of new hair follicles meaning that unwanted new hair follicles will have to be removed or destroyed by electrolysis or other means before they will go away.

86. In both men and women, testosterone often produces weight gain and an increase in one’s appetite.

87. In women, high levels of testosterone can cause a permanent enlargement of the clitoris, which can be extremely uncomfortable and make even wearing pants painful.

88. In men, the introduction of supplemental testosterone to the body has a cascading effect on the hormone production centers within a man's body, which, with sufficient use, can ultimately result in the end of a man's ability to produce his own testosterone.

89. Additionally, in men, prolonged exposure to high levels of testosterone can cause testicular atrophy, impotency, and the development of breast tissue similar in appearance to that found in women.

BACKGROUND ON HORMONE REPLACEMENT THERAPY

90. Hormone replacement is a therapy designed to restore some of the hormones lost to the aging process or as a result of surgical menopause. While sex hormone levels in men decrease with age, hormone replacement therapy is most commonly associated with and prescribed to menopausal women.

91. The amount of estrogen produced by a woman's body is regulated by the ability of the ovaries to respond to stimulation. When the ovaries are no longer able to produce estrogen, menstruation stops and this is known as menopause.

92. Menopause is associated with a variety of physical symptoms including hot flushes, painful intercourse due to vaginal dryness from loss of lubrication and loss of connective tissue in the vaginal wall resulting in decreased elasticity in the vagina, and increased risk of bone loss or osteoporosis. A hot flush is a sudden feeling of heat that spreads over the face and body. During a hot flush, a woman may break out in a sweat or her skin may redden. Hot flushes can last from a few seconds to several minutes or longer. Hot flushes may occur a few times a month, or several times a

day, and they can occur at any time, day or night. When they occur at night, they are known as “night sweats.”

93. For some women who experience moderate to severe hot flushes, vaginal dryness, or osteoporosis, hormone replacement therapy may be appropriate as a treatment option.

94. Historically, the estrogen that has been used in traditional hormone replacement therapy regimens has been conjugated equine estrogen (“CEE”), which blends many different forms of estrogen from the urine of a pregnant horse, and a progestin (usually MPA) for women with intact uteri.

95. These traditional HRT products, such as Premarin, Prempro, and Premphase, and others have been approved and indicated for use by the FDA at the *lowest* effective dose for the *shortest* duration possible consistent with the treatment goals of the individual patient to treat moderate to severe night sweats or hot flushes, vaginal dryness, and osteoporosis, though the FDA encourages practitioners to consider other treatment options first because of the serious health risks associated with HRT.

96. More recently, some pharmaceutical companies have developed an estradiol skin patch. This is usually coupled with progesterone in oral tablet form in women who still have their uteri.

97. No pharmaceutical company manufactures a hormone replacement therapy product for women that combines estrogen, progesterone, and mega-doses of testosterone.

98. No pharmaceutical company manufactures a hormone replacement therapy product for men that includes mega-doses of testosterone.

99. Some women have absolute contraindications to hormone replacement therapy that compound existing risk. These contraindications mean that the therapy is inappropriate and may result in additional increased health risks or increased risk of death, including women who have had breast or endometrial cancer, and women with a history of thromboembolic disease such as deep vein thrombosis or pulmonary embolism.

100. Prior to 1990, the main use of HRT in post-menopausal women was to treat symptoms of menopause and to prevent osteoporosis.

101. In the 1990s, following a series of observational studies and the promotion of purported cardiac benefits by commercial pharmaceutical manufacturers, medical doctors began to increasingly prescribe HRT to prevent coronary heart disease.

102. The National Institutes of Health, an agency within the United States Department of Health and Human Services, thought that the use of HRT to prevent coronary heart disease exceeded the scientific evidence, and initiated the Women's Health Initiative ("WHI"), a multi-year clinical study testing 16,000 women ages 50 to 79, to test the hormones covered by prior observational studies—namely CFE and MPA.

103. The WHI study tested estrogen alone and estrogen used in combination with progestin, both delivered orally

104. The WHI study found that neither estrogen-only nor the combination therapy protected women from coronary heart disease.

105. In 2002, NIH stopped the WHI combination trial study early for ethical concerns because of data showing an increased risk of breast cancer, heart disease, stroke, and blood clots among participants, which crossed the agreed-to patient risk threshold for breast cancer. The WHI

combination trial study also showed no protection against mild cognitive impairment, and actually showed an increased risk of dementia.

106. Likewise in 2004, the NIH also stopped the estrogen-only trial prematurely because of data showing an increased risk of stroke, increased risk of blood clots, and no benefit for coronary heart disease among participants.

107. As a result of the WHI study, the FDA added a black box warning to Premarin, a CEE product produced by Wyeth Pharmaceuticals, Inc. (later purchased by Pfizer Pharmaceuticals, Inc.), Prempro, a combination CEE and MPA tablet also produced by Wyeth Pharmaceuticals, Inc. (later purchased by Pfizer Pharmaceuticals, Inc.), and Premphase, another combination conjugated estrogen and medroxyprogesterone product produced by Wyeth Pharmaceuticals, Inc. (later purchased by Pfizer Pharmaceuticals, Inc.), which states:

Cardiovascular and other risks

Estrogens with or without progestins should not be used for the prevention of cardiovascular disease. The Women's Health Initiative (WHI) reported increased risks of myocardial infarction [heart attack], stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women during 5 years of treatment with conjugated equine estrogens (0.625 mg) combined with medroxyprogesterone acetate (2.5 mg) relative to placebo) Other doses of conjugated estrogens and medroxyprogesterone acetate and other combinations of estrogens and progestins were not studied in the WHI, and, in the absence of comparable data, these risks should be assumed to be similar. *Because of these risks, estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.* (emphasis added)

108. After stopping the WHI study, the NIH continued to collect follow-up study data from participants to evaluate the effects of stopping the combination CEE plus progesterone therapy. Follow-up information for the period July 8, 2002, to March 31, 2005, was available on 95% of the women who had taken combination hormone therapy.

109. Based on the follow-up analysis of combination therapy users, some of the health effects such as an increased risk of heart disease appeared to diminish following cessation of the therapy, but overall risks—including risks of stroke, blood clots, and breast cancer—remained high.

110. Based on this data, the WHI's global index that summarized risk and benefits was unchanged, showing that the health risks exceeded the health benefits from the beginning of the study through the end of the three-year follow-up period. The follow-up after stopping the study confirmed the WHI's main conclusion that combination therapy should not be used to prevent disease in healthy, post-menopausal women.

BACKGROUND ON BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

111. In 2002, the same year as the WHI study stopped, the United States Supreme Court, in *Thompson v. Western States*, 535 U.S. 357 (2002), affirmed a Ninth Circuit ruling striking down a prohibition under the FDA Modernization Act that prohibited compounding pharmacies from advertising or promoting specific compounding drugs.

112. Following the 2002 ruling and other rulings restricting FDA-enforcement of compounding pharmacies, the fallout from the WHI study, as well as support from BHRT celebrity proponents like Suzanne Somers (whom Defendant HRC Medical and Defendant Dan Hale have referenced approvingly), compounding pharmacies and BHRT providers began to market BHRT much more aggressively. Presumably, this more aggressive marketing was a result of some combination of a perceived low-risk of claim enforcement by the FDA, the increasing number of baby boomers reaching menopause or andropause, the fear these consumers had about commercial pharmaceutical hormone replacement therapy from news reports about the WHI study termination, and because of the increased consumer receptiveness to “natural” or “organic” marketing claims.

113. As a result of aggressive marketing campaigns created by alternative regimen BHRT providers and compounding pharmacists, the FDA and many well-respected medical societies, entities, and individuals have publicly responded by challenging the substantiation for these claims in articles and position statements directed to consumers and other medical professionals.

114. For example, the FDA has stated the following:

‘A natural, safer alternative to dangerous prescription drugs’
‘Can slim you down by reducing hormonal imbalances’
‘Prevents Alzheimer’s disease and senility’

All of these claims have been made by marketers of compounded “bio-identical” hormones, also known as “bio-identical hormone replacement therapy” (BHRT). *But these claims are unproven. FDA is concerned that claims like these mislead women and health care professionals, giving them a false sense of assurance about using potentially dangerous hormone products. . . .*

Myth: “Bio-identical” hormones are safer and more effective than FDA-approved [Menopausal Hormone Replacement Therapy] drugs.

Fact: *FDA is not aware of any credible scientific evidence to support claims made regarding the safety and effectiveness of compounded “BHRT” drugs. ‘They are not safer just because they are ‘natural,’”* says Kathleen Uhl, M.D. Director of FDA’s Office of Women’s Health. . . . (emphasis added).

115. The Endocrine Society, a well-respected medical society composed primarily of doctors who study the effect of hormones on the human body, has said the following about BHRT:

“Bio-identical hormones,” particularly estrogen and progesterone, have been promoted as safer and more effective alternatives to more traditional hormone therapies, often by people outside of the medical community. *In fact, little or no scientific and medical evidence exists to support such claims about “bioidentical hormones.”* Additionally, many “bioidentical hormone” formulations are not subject to FDA oversight and can be inconsistent in dose and purity. As a result of unfounded but highly publicized claims, patients have received incomplete or incorrect information regarding the relative safety and efficacy of hormone preparations that are referred to as “bioidentical.” . . . *No medical or scientific evidence exists to support the idea that the adverse and/or beneficial effects found in the WHI results from the molecular structure of the synthesized hormones, nor is there any sound scientific evidence to show that a different or “customized” dose of*

hormones would have changed the outcome. If dosage and purity were equal, then all estrogen-containing hormone therapies, "bioidentical" or "traditional," would be expected to carry essentially the same risks and benefits . . . [Bioidentical providers] also allege that customized "bioidentical hormones" are safer and more effective than modified hormones synthesized under close FDA supervision. These claims are not supported by scientific data. . . . The Endocrine Society is concerned that patients are receiving potentially misleading or false information about the benefits and risks of "bioidentical hormones. . . ." (emphasis added)

116. Similarly, the Committee on Gynecologic Practice of the American Congress of Obstetricians and Gynecologists ("ACOG") issued a position statement in November 2005, which was reaffirmed in 2007, stating the following, in relevant part:

Most compounded products have not undergone rigorous clinical testing for safety or efficacy, and issues regarding purity, potency, and quality are a concern. Compounded hormone products have the same safety issues as those associated with hormone therapy agents that are approved by the U.S. Food and Drug Administration and may have additional risks intrinsic to compounding. There is no scientific evidence to support claims of increased efficacy or safety for individualized estrogen or progesterone regimens. (emphasis added)

117. More recently, ACOG's Committee on Gynecologic Practice and the American Society for Reproductive Medicine Committee issued a position paper (updating the 2005 and 2007 statements), which concludes:

- *Evidence is lacking to support superiority claims of compounded bioidentical hormones over conventional menopausal hormone therapy.*
- *Customized compounded hormones pose additional risks. These preparations have variable purity and potency and lack efficacy and safety data.*
- *Because of variable bioavailability and bioactivity, both underdosage and overdosage are possible.*
- *Conventional hormone therapy is preferred over compounded hormone therapy given the available data.*
- *Despite claims to the contrary, evidence is inadequate to support increased efficacy or safety for individualized hormone therapy regimens based on salivary, serum, or urinary testing. (emphasis added)*

118. The Council on Science and Public Health within the American Medical Association has stated the following, in relevant part:

Based on systematic reviews conducted by the IOM and the Endocrine Society, as well as the Council's evaluation of seven more recent randomized, placebo-controlled clinical trials, *definitive evidence of the value of testosterone as an antiaging therapy in older men does not exist, and further research is indicated.* Estrogens with or without progestins are highly effective in treating the vasomotor symptoms associated with menopause. *However, primarily based on the Women's Health Initiative (WHI), a large, randomized, placebo-controlled, primary (chronic condition) prevention clinical trial in postmenopausal women, the long-term use of estrogens with or without progestins causes more risks than benefits in [these] populations. No credible scientific evidence exists on the value of so-called "bioidentical hormones," and there are concerns about their purity, potency and quality because they are not approved by the FDA.* (emphasis added)

119. The North American Menopause Society ("NAMS") has likewise stated the following, in relevant part:

The US Food and Drug Administration (FDA) has ruled that compounding pharmacies have made claims about the safety and effectiveness of BHT unsupported by clinical trial data and considered to be false and misleading. . . . *NAMS recommends that filled prescriptions for BHT should include a patient package insert identical to that required for products that have regulatory agency approval. In the absence of efficacy and safety data for any specific prescription, the generalized benefit-risk ratio data of commercially available HT products should apply equally to BHT.* For the vast majority of women, regulatory agency-approved HT will provide appropriate therapy without the risks and cost of custom preparations. (emphasis added)

120. The American Association of Clinical Endocrinologists ("AACE") has echoed this skepticism, stating the following, in relevant part:

AACE expresses concerns about unproven but highly publicized claims about the alleged higher safety and efficacy of compounded bioidentical hormones. In addition, from a clinician's perspective, AACE believes that potentially serious dangers of BH use have not been sufficiently exposed. The primary concern about bioidentical hormone use is patient safety. These substances have not been shown within the medical community to be clinically effective. In addition, utilization of these formulations may be associated with various risks inherent to the compounding

process. *The exaggerated claims about efficacy and safety of BH are made despite clear evidences of variability in potency, high potential for contamination and impurity of those preparations. Also, some unorthodox clinical practices utilized by BH promoters are quite worrisome.* Those practices include individualized dosing frequently based upon unproven testing methods such as salivary assays, which has not been validated. Finally, the cost effectiveness of this modality requires careful consideration.

Exaggerated Claims about Efficacy and Safety

The public has been persuaded that treatment with bioidentical hormones has to be safer, more effective, and free of side effects since those preparations are "natural." Those are the main claims of the proponents of the "bioidentical" approach to menopausal hormone therapy. Those assertions have been made in popular publications or disseminated via the Internet. They have not been properly peer-reviewed or subjected to formal scientific scrutiny. A systematic review of the current scientific literature does not appear to support these notions. Well designed studies in this area are needed. Until evidence-based, scientific studies are available, the existence of meaningful differences between "bioidentical" and conventional hormones remains to be established. (emphasis added)

121. Dr. Mary Gallenberg, an assistant professor at the Mayo Clinic's College of Medicine and a consultant in the Department of Obstetrics and Gynecology at the Mayo Clinic, has echoed this sentiment, stating the following, in relevant part:

Are bioidentical hormones safer and more effective than hormones used in traditional hormone therapy for menopause symptoms? Answer from Mary M. Gallenburg, M.D. *No they aren't.* The term 'bioidentical' means the hormone in the product are chemically identical to those your body produces. In fact, they are – but so are the hormones used in many FDA-approved hormone replacement products. *According to the Food and Drug Administration (FDA) and several medical specialty groups, bioidentical hormones may be riskier than are hormones used in standard hormone therapy, and there's no evidence they're any more effective . . .* Some women may benefit from nonstandard doses and forms of hormones in bioidentical hormone preparations, *but there is almost no scientific support for an advantage of these compounds over common commercially produced preparations.* (emphasis added)

122. Likewise, the American Cancer Society has stated the following, in relevant part:

The word bioidentical is sometimes used to describe versions of estrogen and progestin with the same chemical structure as those found naturally in people. The use of these hormones has been marketed as a safe way to treat the symptoms of menopause. *It is important to realize that although there are few studies comparing*

“bioidentical” or “natural” hormones to synthetic versions of hormones, there is no evidence that they are safer or more effective. The use of these bioidentical hormones should be assumed to have the same health risks as any other type of hormone therapy. (emphasis added)

BACKGROUND OF DEFENDANT HRC MEDICAL’S ALTERNATIVE REGIMEN OF BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

123. Defendant HRC Medical’s bio-identical hormone replacement therapy is a purported alternative to traditional commercial hormone replacement therapy, which supplies the body with hormones depleted through the aging process.

124. Defendants use the term “bio-identical” to mean that the hormones contained in BHRT pellets are molecularly identical to the hormones that are naturally produced in men and women. While some commercial hormone products produced by pharmaceutical companies may meet this definition, the term has been used so often by those who provide alternative regimens of hormone replacement therapy that the word “bioidentical” has become shorthand for the alternative regimens of hormone replacement therapies themselves.

125. Aside from “bio-identical,” Defendants have also used the term “bio-available” or “bio-equivalent” to describe Defendant HRC Medical’s BHRT. For purposes of this Complaint, “BHRT” encompasses all of these terms.

126. Defendant HRC Medical’s BHRT differs from the HRT products produced by pharmaceutical companies at least six fundamental ways. First, Defendant HRC Medical’s BHRT for women includes mega-doses of testosterone which are not found in any HRT product. Second, Defendant HRC Medical’s BHRT, in essence, treats blood hormone levels outside Defendants’ elevated target ranges as pathological conditions as opposed to focusing on symptom relief and global or specific risks to the consumer. Third, unlike HRT, Defendant HRC Medical encourages a

long-term, perpetual use of BHRT, which dramatically increases safety concerns and risks. Fourth, unlike HRT, Defendant HRC Medical's BHRT is marketed to healthy, young women in their twenties, thirties, and forties who are not close to menopause. Defendant HRC Medical's BHRT is also marketed to healthy, young men in their teens, twenties, thirties, and forties. Fifth, Defendant HRC Medical's BHRT is created by compounding pharmacies that, unlike pharmaceutical companies, are not subject to FDA regulations governing good manufacturing practices, which are designed to improve quality control by standardizing potency, eliminating or reducing the presence of foreign contaminants, and creating a consistent end-product. Defendant HRC Medical has had quality control problems with the hormone pellets it has used—problems of which Defendant Don Hale and Defendant Dan Hale have been aware. Sixth, unlike traditional HRT, for the vast majority of Defendant HRC Medical's BHRT consumers, the decision whether BHRT will be offered to the consumer is made *before* he or she ever sets foot in the door.

127. Generally, BHRT promoters, including all Defendants, assert that the purported molecular symmetry with naturally-produced hormones makes BHRT safer and more effective than traditional HRT.

128. Defendant HRC Medical's BHRT includes estrogen and testosterone delivered through pellets inserted subcutaneously. For most women, Defendant HRC Medical's BHRT usually includes micronized progesterone in tablet form—even for women who have had hysterectomies.

129. Defendant HRC Medical also offers "free" B-12 shots with their BHRT package. Defendant HRC Medical does this because the B-12 shots are very inexpensive, but also because the shots make the consumer feel something after the first pellet insertion.

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129. Defendant HRC Medical also offers “free” B-12 shots with their BHRT package. Defendant HRC Medical does this because the B-12 shots are very inexpensive, but also because the shots make the consumer feel something after the first pellet insertion.

130. The estrogen component for Defendant HRC Medical's BHRT consists of estradiol in pellet form, which is delivered subcutaneously. When estrogen is administered, the estradiol pellets are inserted in the hip in 3 milligram to 18 milligram doses, which is many times higher than the low-dose estrogen commonly given as part of HRT.

131. The progesterone component for Defendant HRC Medical's BHRT consists of micronized progesterone in tablet form, which is meant to be dissolved under the tongue.

132. Regardless of the estradiol or testosterone dose, Defendant HRC Medical's progesterone component is most often delivered as a 200 milligram tablet, although it is sometimes dosed in smaller amounts like 50 milligrams or 100 milligrams.

133. As part of Defendant HRC Medical's BHRT, Defendant HRC Medical even provides progesterone to women who have had hysterectomies. As an example, Defendant HRC Medical has stated the following in its Patient Information Packet, in relevant part:

If you've had a Hysterectomy: Take progesterone every night before bed (your individual dosage will be determined and discussed with you by the nurse.)

134. Defendant HRC Medical's BHRT also includes testosterone in pellet form delivered subcutaneously. In women, the testosterone pellet dose can be up to 200 milligrams for one implant. In men, the testosterone dose can be up to 3,200 milligrams for one implant.

135. Although blood levels are not a perfect measurement to evaluate testosterone, Defendant HRC Medical effectively treats blood levels below its high target levels, including hormone blood levels found in the vast majority of normal, healthy individuals, as a pathological condition.

136. The range of testosterone in 95% of women is less than 10 ng/dL and up to 70 ng/dL, although some laboratories use ranges between 0 ng/dL and 65 ng/dL. As evidenced by numerous

internal documents, Defendant HRC Medical's target range of testosterone for *women* is between 250 ng/dL and 300 ng/dL, which is in the normal *male* range for testosterone. The testosterone actually found in female consumers of Defendant HRC Medical's BHRT is often significantly higher than even Defendant HRC Medical's target range, which is already in the normal male range.

137. Defendant HRC Medical has advised in correspondence with a female consumer:

"Testosterone Total needs to be between 250 – 300 ng/dL".

138. The reference range for testosterone in healthy, normal men is between 200 ng/dL and 700 ng/dL. For testosterone, Defendant HRC Medical's target range has been significantly higher than the highest end of the range.

139. For example, Defendant HRC Medical has stated the following, in relevant part:

Our target blood range (the range at which we see the highest degree of symptom relief with the lowest degree of side effects) is *1100 ng/dl to 1400 ng/dl*. Some men will feel best at levels below 1100 ng/dl and some will feel best at levels higher than 1400 ng/dl.

and elsewhere:

HRC has conducted a study of 182 men from one of our Centers who were satisfied with their treatments. "Satisfied" means they achieved symptom relief with minimal side effects and therefore renewed their treatment for another year. We analyzed 940 measurements. The Mean testosterone level attained in this sample was 1083.7 while the Median level was 1075.5. The "high" end was 1700. . . .

140. Because of the way the body responds to sex hormones, including through conversion of one hormone into another and through the potentially contradictory effects of hormones given in combination, a cocktail of hormones containing high doses of estradiol and high doses of testosterone in pellet form delivered subcutaneously along with micronized progesterone delivered through oral tablet would have to be studied as a whole to determine any benefits, efficacy, and safety or to make comparison claims with traditional HRT.

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141. There is no competent and reliable scientific evidence that has tested the efficacy, benefits, or safety of estradiol and testosterone delivered subcutaneously in pellet form with or without micronized progesterone delivered orally.

142. Further, there is no competent and reliable scientific evidence that establishes equivalence with or superiority of estradiol and testosterone delivered subcutaneously in pellet form with or without micronized progesterone delivered orally over traditional HRT products—including specific claims of equivalence or superiority with respect to safety, risks, or side effects.

143. There is no competent and reliable scientific evidence to support efficacy, benefit, or safety claims of a therapy that produces supraphysiologic levels of estrogen alone or in combination with supraphysiologic levels of testosterone and/or progesterone.

144. There is no competent and reliable scientific evidence that has tested the efficacy, benefits, or safety of supraphysiologic levels of testosterone in men and women including supraphysiologic of testosterone delivered subcutaneously in pellet form in either men or women.

OVERVIEW OF HOW DEFENDANT HRC MEDICAL'S BHRT HAS BEEN SOLD

145. After hearing advertisements for Defendant HRC Medical's BHRT, consumers call in to set up a "free" consultation. Defendant HRC Medical gives first preference in scheduling consultations to its most successful sales consultant, who has no or only negligible hormone-related or medical training on hormones, and is paid on a full or partial commission basis.

146. At least two of Defendant HRC Medical's most successful sales consultants, Amanda Garrett and Andrea Bernard, were paid on a 100% commission basis—meaning that they did not get paid unless they made a sale. Andrea Bernard, Defendant HRC Medical's most successful sales consultant, stated that she was under "very strong pressure to sell constantly" and that her sales conversion ratios for BHRT were monitored constantly by Defendant Don Hale and his son, Dane Hale.

147. At the "free" consultation, Defendant HRC Medical's and Defendant HRC Management Midwest's sales consultants give consumers the sales pitch about the BHRT. The sales consultants then ask consumers to fill out a symptom relief chart that purports to catalog symptoms associated with hormone imbalances. The list of symptoms, like "tiredness" and "poor focus," are intentionally chosen by Defendants to apply to the greatest number of people. Absent rare circumstances, one checked box means that the sales consultant should offer the consumer the BHRT. Some, but not all consumers, are then asked to fill out a medical history form.

148. Defendants have instructed sales consultants to ask consumers to sign non-refundable contracts for Defendant HRC Medical's BHRT either through a lump sum payment or through financing. The non-refundable contracts usually cost between \$2,000 and \$3,000 for women, and includes a year's worth of hormone pellet inserts. The non-refundable contracts for men usually cost

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between \$3,000 and \$4,000. While Defendant HRC Medical offers *a la carte* pricing for one pellet implant (usually \$1,100 per implant), this price is disproportionate to what the per-pellet implant would be in the annual package and is presumably designed to drive consumers towards the more expensive annual package.

149. Defendant Don Hale, on behalf of Defendant HRC Medical, established prices for Defendant HRC Medical's BHRT.

150. For the vast majority of consumers, the sales consultant takes the consumer back to have his or her blood hormone levels drawn *after signing the non-refundable contract and paying for a year's worth of BHRT*. The consumer leaves the "free" consultation after giving blood for laboratory tests that will supposedly indicate whether the consumer is a candidate for BHRT.

151. Because Defendant HRC Medical uses target blood hormone ranges that are well-outside the normal ranges, Defendant HRC Medical almost always finds that the consumer's hormone levels are deficient—particularly for testosterone.

OVERVIEW OF DEFENDANT HRC MEDICAL'S BHRT ADVERTISING

152. Defendant HRC Medical has advertised its BHRT heavily on television, radio, online, and in print in Tennessee.

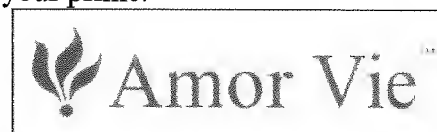
153. Defendants market their BHRT to practically everyone over the age of 18.

154. As an example of this all-encompassing marketing strategy, in a March 31, 2009, press release, which quotes Defendants Dan Hale and Don Hale on behalf of Defendant HRC Medical, Defendant Don Hale is quoted as stating, "We have had a very large range of age [sic] of people needing hormone replacement—from ages 22 to 91!"

155. Other examples can be seen in the “Amor Vie Test,” an interactive portion of Defendant HRC Medical’s website, www.hrcmedical.com, and its own standalone site, www.amorvietest.com. The Amor Vie Test asks the user to fill in his or her age, sex, and then the severity of his or her symptoms on a scale of 1 through 10 with 1 being the very lowest and 10 being the most severe. The symptoms asked about include the following: Depression / Mood Swings, Hot Flashes / Night Sweats, Low Libido / Low Sex Drive, Low Energy / Fatigue, Weight Gain / Weight Control, Painful Intercourse / (ED), and Sleep Disorders.

156. If a consumer types in age 30 and all ‘1s’ for symptom severity, *the lowest amount possible on the scale*, Defendant HRC Medical still asks the consumer to call to set up a consultation with the sales consultant paid on 100% commission through the following message, which is quoted and shown below in an excerpt as Figure 9:

You are probably at the start of experiencing Moderate symptoms of hormone deficiency that have begun to affect some aspects of the quality of your life. Call us at HRC for a free consultation so you can learn the “tell tale” signs of hormone depletion. Let HRC begin to Restore! what you are losing and Renew! your quality of life to what you had in your prime.



RESTORE! RENEW! REJOICE!

You are probably at the start of experiencing Moderate symptoms of hormone deficiency that have begun to affect some aspects of the quality of your life. Call us at HRC for a free consultation so you can learn the “tell tale” signs of hormone depletion. Let HRC begin to Restore! what you are losing and Renew! your quality of life to what you had in your prime.

Zip Code *

E-Mail Address *

Submit

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Fig. 9 (Not to Scale)

157. Under the same test, if the consumer lists his or her age as 20 and types in all 2s, *the next lowest ranking amount for every symptom*, Defendant HRC Medical sends the consumer the same message as above.

158. Defendant HRC Medical has advanced the same all-encompassing marketing message in other advertisements for its BHRT. For example, in an advertisement for Defendant HRC Medical's BHRT, Defendant HRC Medical states: "Bio-Identical Hormones are providing spectacular results for women of all ages."

159. In the same advertisement for Defendant HRC Medical's BHRT, Jennifer Hale, Defendant Don Hale's daughter-in-law, states the following, "*Now, I realize that it is not only for women going through menopause.*"

160. Overall, most of Defendant HRC Medical's advertising about BHRT is directed at women, but Defendant HRC Medical also directs a significant portion of advertising to highlight its BHRT program for men as well.

161. Defendant HRC Medical advertises its BHRT heavily on local television and radio in the Nashville and, to a lesser extent, the Knoxville media market.

162. Throughout its operation of the Memphis HRC Medical office, Defendant HRC Management Midwest has used advertising, promotional, and contractual materials provided by Defendant HRC Medical and has directed consumers to the website, www.hrcmedical.com, owned and operated by Defendant HRC Medical.

163. Prior to the time when Defendant HRC Management Midwest owned and operated the Memphis office, Defendant HRC Medical provided the Memphis office with advertising,

promotional, and contractual materials, which directed consumers to the website, www.hrcmedical.com.

164. Defendant HRC Medical has produced television commercials about its BHRT which have aired in the Nashville and Knoxville television markets about its BHRT that have aired during local-only programs, local advertising slots on national programs, or before videos posted by local television affiliates on their websites.

165. Since its inception, Defendant HRC Medical has advertised on every major television affiliate in the Nashville area.

166. On at least 40 occasions, Defendant HRC Medical has paid for advertisements on Nashville television affiliates that last between 3 and 5 minutes. These longer advertisements have occurred at least on April 12, 2010, August 24, 2010, September 8, 2010, May 23, 2011, June 21, 2011, June 22, 2011, July 21, 2011, July 27, 2011, July 28, 2011, August 11, 2011, August 22, 2011, September 21, 2011, September 29, 2011, October 3, 2011, October 24, 2011, October 26, 2011, November 17, 2011, November 22, 2011, December 5, 2011, December 7, 2011, December 15, 2011, January 23, 2012, January 25, 2012, February 7, 2012, February 15, 2012, February 20, 2012, March 14, 2012, March 19, 2012, April 10, 2012, April 2, 2012, May 3, 2012, May 8, 2012, May 21, 2012, June 4, 2012, June 15, 2012, June 26, 2012, July 10, 2012, and July 23, 2012.

167. Defendant Dan Hale has appeared on these longer advertisements for Defendant HRC Medical's BHRT at least on July 21, 2010, July 28, 2010, August 24, 2010, September 21, 2010, September 21, 2011, October 26, 2011, November 17, 2011, December 7, 2011, and January 25, 2012.

168. Defendant Don Hale has appeared on these longer advertisements for Defendant HRC Medical's BHRT at least on September 8, 2010, May 3, 2012, May 8, 2012, and July 10, 2012.

169. Defendant HRC Medical has paid television affiliates for advertising on the affiliate's website including: www.wsmv.com/category/212688/hrc-medical.

170. Defendant HRC Medical has been listed as a chief sponsor of a morning program for a Nashville television affiliate. As part of the advertising package, Defendant HRC Medical's logo has appeared alongside the program's logo or has been rotated with the morning show's logo during the broadcast and in web videos of the broadcast.

171. Defendant HRC Medical also has advertised its BHRT for men on sports talk radio and other outlets in Middle and East Tennessee.

172. Defendant HRC Medical owns, operates, and controls www.hrcmedical.com, www.amorvietest.com, and www.hrcmeds.com.

173. Defendant HRC Medical directs the vast majority of its other advertisements to the website, www.hrcmedical.com, including those for other franchises.

174. Defendant HRC Medical's website has had several iterations, which have all made representations about the purported safety, efficacy, benefits, side effects, and risks of Defendant HRC Medical's BHRT and its purported superiority over traditional HRT, and which have all failed to clearly and conspicuously disclose serious side effects and risks associated with their BHRT.

175. Defendant HRC Medical operates promotional Facebook accounts for its Nashville office and for its Knoxville office, including www.facebook.com/pages/HRC-Medical-Center-of-Nashville/267275500430 and www.facebook.com/pages/HRC-Medical-Center-of-Knoxville/238402456184636.

176. Defendant HRC Medical also operates a Facebook account for Defendant HRC Management Midwest for the Memphis office, including www.facebook.com/pages/HRC-Medical-Center-of-Memphis/120860564682635?ref=ts.

177. Defendant Dan Hale has written posts on both Defendant HRC Medical's Nashville and Knoxville Facebook pages about Defendant HRC Medical's BHRT.

178. Defendant Don Hale has written posts on Defendant HRC Medical's Nashville Facebook page about Defendant HRC Medical's BHRT.

179. Defendant HRC Medical has posted advertisements for its BHRT on YouTube under the YouTube account name HairRestorationCenter, HRCMedicalGR, and HRCMedical, which have featured Defendant Dan Hale and Defendant Don Hale.

180. Defendant HRC Medical's YouTube and other online videos are available online by themselves, and are also linked or embedded within websites, Facebook accounts, or other web-based media controlled by Defendant HRC Medical.

181. Defendant Dan Hale has also written a series of articles about Defendant HRC Medical's BHRT that have been distributed in hard copy and electronic form, on Defendant HRC Medical's website, and Defendant HRC Medical's Facebook accounts for its Tennessee offices. Among other things, these articles speak to the purported safety, benefits, efficacy, risks, and side effects of Defendant HRC Medical's BHRT, the purported safety, benefits, efficacy, risks, and side effects of Defendant HRC Medical's BHRT compared with traditional hormone replacement therapy regimens, and state that Defendant HRC Medical's BHRT restores a consumer's hormone levels to the levels he or she had in his or her twenties or thirties.

182. Defendant HRC Medical and, as set forth below, Defendants Don Hale and Dan Hale, have made a host of claims about Defendant HRC Medical's BHRT, which appear frequently in its advertisements.

EXPRESS CLAIMS THAT NOT REPLACING ONE'S HORMONES IS UNSAFE

183. Both Defendant HRC Medical and Defendant Dan Hale, acting on behalf of Defendant HRC Medical, have falsely, deceptively, and/or without adequate substantiation claimed on multiple occasions in advertisements for Defendant HRC Medical's BHRT that it is unsafe for an individual *not* to replace one's hormones.

184. For example, in an advertisement for Defendant HRC Medical's BHRT on WSMV, Nashville's local NBC affiliate, Defendant Dan Hale stated the following:

Oh my, see the bad thing about hormones is this: It is not good not to replace your hormones. In other words, some people say, "*Is this safe?*" *It's more than safe. It is not safe not to replace your hormones.*" (emphasis added)

185. In a different advertisement on Nashville's NewsChannel 5's midday program, Defendant Dan Hale stated the following about Defendant HRC Medical's BHRT:

The bio-identical means it's biologically identical to the hormones you had when you were 20 years old. So, they perform exactly the same way that our hormones did years ago, *so not only they're safe, it is not safe not to replace them.* So, it's actually a health benefit to us. I know we like to talk about how we feel and all that, but actually the hormones help us with our health in every area of our life, *so it's not safe not to have your hormones balanced.* (emphasis added)

186. In another advertisement for Defendant HRC Medical's BHRT on WSMV, Defendant Dan Hale and WSMV's Kacy Haggerty engaged in the following dialogue:

KACY HAGGERTY: So is "all natural" a really good option for people?

DR. HALE: *It's not even, it's not an option. What I'm saying is that without hormones, it's not safe. People sometimes say is this safe? I'm saying to you, it's not*

safe is like, "Should I wear a safety belt?" Of course. You know it's not safe not to keep your hormones where they should be.

KACY HAGGERTY: And, again, you've seen tons of success in all of this?

DR. HALE: Oh my. *Everyone.* (emphasis added)

187. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that it is unsafe to not replace one's hormones using Defendant HRC Medical's BHRT or otherwise.

188. Clinical studies, research, and/or trials do not show that it is unsafe not to replace one's hormones, rather the weight of the scientific evidence shows the opposite, namely that replacing one's hormones, while appropriate for some, carries with it substantial potential risks to one's health.

EXPRESS CLAIMS THAT DEFENDANT HRC MEDICAL'S BHRT IS SAFE

189. Defendant HRC Medical, Defendant Don Hale, and Defendant Dan Hale have falsely, deceptively, and/or without adequate substantiation represented, without qualification, on multiple occasions that Defendant HRC Medical's BHRT is safe, absolutely safe, or completely safe.

190. In a brochure handed out to consumers at the Knoxville, Nashville, and Memphis offices in Tennessee, excerpted below as Figure 10, Defendant HRC Medical has stated the following about its BHRT:

IS THIS SAFE? Absolutely. They actually have been shown to have very preventive and protective qualities with regard to cancer.

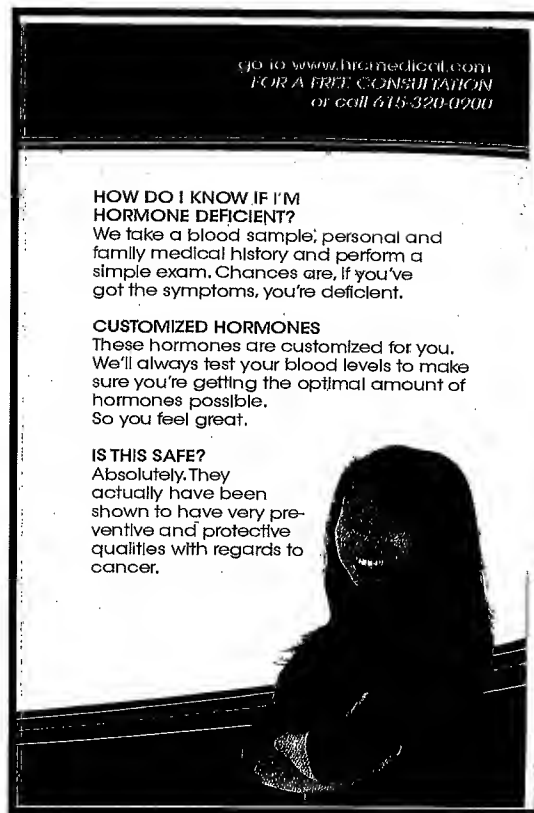
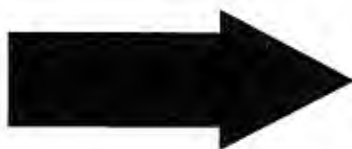


Figure 10 (Not to scale)

191. Similarly, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following:

Bio-identical hormones are safe. They're not the kind of hormones that are unsafe.
(emphasis added)

192. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following:

Bio-identical hormones are completely safe. (emphasis added)

193. In advertisements for Defendant HRC Medical's BHRT, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part:

What everyone should understand is that bio-identical hormones are very safe. . . .
(emphasis added)

194. On July 21, 2011, and in August 2011, Defendant HRC Medical stated the following on its Facebook page for its Nashville office:

Is it safe? Yes. Bio-equivalent hormone therapy is the safest form of hormone treatment available. (emphasis added)

195. Likewise, in an advertisement for Defendant HRC Medical's BHRT, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in relevant part:

Go on the Internet and read about bio-identical hormones and you'll see that there's a lot of information out there. *All of it is positive. You're not going to see anything that says that bioidentical hormones causes anything bad at all. It's just not there. If there's anything bad about something it's going to show up on the Internet as you know.* You're not going to find it because bio-identical hormones you have are the same kind of hormones you had when you were twenty years old. (emphasis added)

196. Similarly, on July 9, 2011, and July 23, 2011, Defendant HRC Medical stated the following on its Facebook page for its Nashville office:

[ERT . . . estrogen replacement therapy] scares most women because they have the impression that all estrogens are dangerous. *Bio-Identical Hormone Replacement Therapy is just the opposite . . .* (emphasis added)

197. Defendant HRC Medical has stated on its website, www.hrcmedical.com, at varying times, the following, in relevant part:

Amor Vie hormone therapy is safe, all natural and effective. . . . Derived from natural sources such as yams or soy, Amor Vie Bio-Identical Hormones provide a safe and natural alternative to women and men with low levels of progesterone, estrogen, and testosterone. (emphasis added) and

Amor Vie therapy allows us to offer you a safe, highly effective [sic] that you can confidently select to optimize and protect your overall health and wellness. (emphasis added)

198. Defendant HRC Medical has stated in advertisements, the following, in relevant part:

Amor Vie therapy using bionatural hormones helps replace these hormone levels to what they were in women when they were in their twenties, safely, without negative potential side effects of synthetic hormones. (emphasis added)

199. On August 12, 2011, Defendant HRC Medical stated the following on its Facebook page for its Nashville office:

TIRED of being TIRED? Get your life back *in a safe*, all natural, and effective manner! At HRC Medical Nashville, we bring freshness back to your life by getting your hormones back in balance. Call (615) 320-0900 to schedule your free consultation today! (emphasis added)

200. On August 25, 2011, and September 2, 2011, Defendant HRC Medical stated the following on its Facebook page for its Nashville office:

Our procedures bring back the hormonal balance your body needs. *Amor Vie therapy is safe*, all natural and effective. (emphasis added)

201. Defendant Don Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part in advertisements aired multiple times on WSMV:

No one can find any evidence that having your hormone levels raised back like they were in their [sic] youth can hurt you in any way if it's done with natural hormones as opposed to synthetic hormones. (emphasis added)

202. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in an advertisement for Defendant HRC Medical's BHRT:

So they – so there are actually no health risks that we've ever been able to determine with the bio-identical hormones. (emphasis added)

203. In advertisements for its BHRT, Defendant HRC Medical has used the tagline: HRC Medical Center Amor Vie Natural. *Safe*. Personalized. (emphasis added)

204. On March 1, 2012, Defendant HRC Medical stated the following on its Facebook page for its Nashville office, in relevant part:

Also, most doctors use synthetic hormones, patches, and creams, where HRC Medical uses Amor Vie and it is a Natural Therapy. *Less side effects and a lot safer*. Tina call your local center for a consultation and they can tell you the *huge difference*. (emphasis added)

205. In advertisements, Defendant HRC Medical has used consumer testimonials who have stated the following, in relevant part:

I was amazed that you know there have been lots of studies and I felt really confident that what I was doing was going to be safe and it was going to be effective and so that's what made me want to go for it. (emphasis added)

206. Elsewhere in advertisements for Defendant HRC Medical's BHRT featuring Defendant Dan Hale and Defendant Don Hale, Defendant HRC Medical has, on multiple occasions, used the word "safe" as the most prominent descriptor for its BHRT, some of which are shown as Figures 11 -14 in screen shots below:

Fig. 11



Fig. 12



Fig. 13



Fig. 14



207. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that it Defendant HRC Medical's BHRT is safe, completely safe, or absolutely safe.

208. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT is safe, completely safe, or absolutely safe.

**EXPRESS CLAIMS THAT DEFENDANT HRC MEDICAL'S BHRT
HAS NO CANCER RISK OR PROTECTS AGAINST CANCER**

209. Defendants HRC Medical and Dan Hale have falsely, deceptively, and/or without adequate substantiation have claimed that Defendant HRC Medical's BHRT involves no cancer risk for consumers or protects against cancer.

210. On a brochure for Defendant HRC Medical's BHRT featuring Defendant Dan Hale's picture and a brief description handed out to consumers in Tennessee, excerpted below as Figure 15, Defendant HRC Medical and Defendant Dan Hale stated the following:

Will Hormones increase my risk of cancer?

Never. Natural Bio-Equivalent Hormones actually are protective. In a study done of 976 females [sic] patients who had the pellet insertions no one developed breast or ovarian cancer secondary to the hormones. (emphasis added)

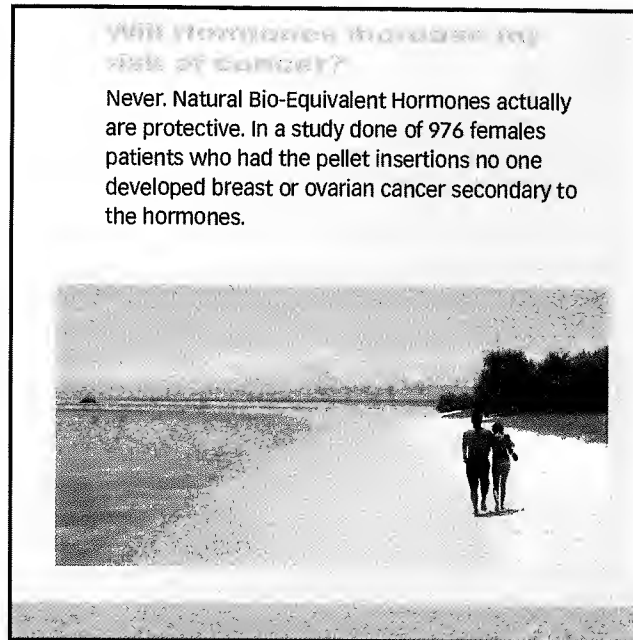


Figure 15 (Not to Scale)

211. On another brochure advertising Defendant HRC Medical's BHRT, Defendant HRC Medical has falsely stated:

IS THIS SAFE? Absolutely. *They actually have been shown to have very preventive qualities with regards to cancer.* (emphasis added)

212. Defendant Dan Hale, on behalf of Defendant HRC Medical, has repeated this false assertion in other formats. In advertisements for Defendant HRC Medical's BHRT, Defendant Dan Hale stated the following:

Bio-identical hormones therapy are [sic] safe. They're not the kind of hormones that are unsafe. The other kind of hormones for hot flashes called conjugated estrogen and they are not safe. *We know that because on the Women's Health Initiative trial, they caused a lot of problems with breast cancer, cervical cancer, heart disease, blood clots. The bio-identical hormones never, ever do that. As a matter of fact, a lot of studies show that probably they're somewhat protective in some of those things.* Thank you very much. (emphasis added).

213. In advertisements for Defendant HRC Medical's BHRT, Defendant Dan Hale has stated the following:

Bio-identical hormones are different than the traditional because bio-identical means biologically identical. That means that they are the same as the hormones that you had when you were twenty years old. I try to visualize it this way. If this is the hormones I had when I was twenty [holds palm up facing sideways] then this is [sic] the hormones that we're putting in [holds up other hand and presses palms together]. These are biologically identical. That means they're different from the synthetic. *The synthetic kind of hormones are the ones that cause breast cancer, cervical cancer, heart disease, blood clots. Go to the website and type in 'Women's Health Initiative' study. You can read about that. You can find out that the bad things made from horse urine. That's conjugated estrogen. The bio-identical do not cause that. They are probably are [sic] somewhat protective.* (emphasis added).

214. The claim that Defendant HRC Medical's BHRT will never increase a user's risk of cancer is false and cannot be reconciled against Defendant HRC Medical and Defendant Dan Hale's claim that the hormones contained in their BHRT are identical to the hormones that the body naturally produces.

215. It is widely accepted and well established that the estrogen that the body naturally produces, in sufficient amounts, increases a woman's risk for developing endometrial cancer (cancer of the lining of the uterus).

216. If Defendant HRC Medical's BHRT is indeed molecularly identical to the estrogen that the body naturally produces, then it will necessarily increase a woman's risk for developing endometrial cancer.

217. Defendant HRC Medical and Defendant Dan Hale have gone further than stating that there is no cancer risk with Defendant HRC Medical's BHRT, by claiming that Defendant HRC Medical's BHRT actually protects against the development of various cancers.

218. In an advertisement aired in Tennessee and made available on YouTube, Defendant Dan Hale stated about Defendant HRC Medical's BHRT, the following:

Well, with the bioidentical hormone replacement therapy, they are actually breast protective. So, it is probably almost impossible to have breast cancer when you're

using this bioidentical hormone replacement therapy, actually breast protective. So I feel good about doing things that are safe and help people at the same time. (emphasis added)

219. In an advertisement aired in Tennessee on Nashville's WSMV, Defendant Dan Hale, on behalf of Defendant HRC Medical, engaged in the following dialogue with Kacy Haggerty of WSMV:

KACY HAGGERTY: [N]ow a lot of people out there are concerned about the safety of hormone replacement therapy. Can you talk about that? Is it safe?

DAN HALE: I'm glad you asked that question. So many people think that aw, it could cause heart attacks, strokes, blood clots, but every time they do those kind of studies they're talking about the synthetic kind. Every study done, there's many hundreds of studies that is [sic] out there that show hormones actually protect it, if it's the kind we had when we were 25 years old. It only makes sense. When you were 25, you were healthiest and when we're 55-60-65, things begin happening to us that we don't like. The reason why is because then we had hormones that are natural. Well, when we replace those hormones that are identical to those hormones then actually they're protected and studies will show that. *There's a lot of protection from Alzheimer's, from breast cancer, cervical cancer, so a lot of good things can happen, but studies confirm what I just told you.*

KACY HAGGERTY: *Good information, sounds very safe.* (emphasis added)

220. Defendant HRC Medical has posted the following on its website, www.hrcmedical.com, about its BHRT:

- Cancer

Synthetic estrogens are associated with 6 different cancers. Vitamin D helps prevent cancer. There are studies which strongly suggest balancing your hormones can deter breast and cervical cancer.

221. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT has no potential risk of cancer or that it can protect against cancer.

222. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT has no potential risk of cancer or that it can protect against cancer.

223. In fact, at least three female consumers of Defendant HRC Medical's BHRT, two of whom provided affidavits, have been diagnosed with breast cancer during or after taking Defendant HRC Medical's BHRT. In one case, the consumer had to have a double-mastectomy. In another instance, the consumer had to undergo a regimen of radiation treatment. While, consistent with its burden under the TCPA, the State does not intend to show a causal connection between these diagnoses and Defendant HRC Medical's BHRT, the incidents are consistent with the possible risks for Defendant HRC Medical's BHRT and wholly inconsistent with Defendant HRC Medical's and Defendant Dan Hale's express statements asserting no cancer risk or cancer protection for its BHRT including for breast cancer.

EXPRESS CLAIMS OF NO OR MINIMAL SIDE EFFECTS

224. Defendant HRC Medical and Defendant Dan Hale, on behalf of Defendant HRC Medical, have falsely, deceptively, and/or without adequate substantiation stated on numerous occasions that Defendant HRC Medical's BHRT has no or minimal side effects.

225. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in an advertisement for Defendant HRC Medical's BHRT:

So they – so there are actually no health risks that we've ever been able to determine with the bio-identical hormones. Now the side effects that I mentioned may be a little bit of facial hair, may be a pimple or something like that, may be spotting if you get the estrogen a little bit too high. All of those side effects that can be changed, that can be corrected by lowering, by correcting the dosage and making sure that the dosages are correct. *So the point is that if we can correct the hormones naturally then there are absolutely no side effects to it at all. . . . So the point is, there are no side effects to these kind of hormones and nothing but good effects.* (emphasis added)

226. In advertisements for its BHRT, Defendant HRC Medical has stated the following, in relevant part:

Progesterone has proven bioavailability and no side effects making it the preferred hormone for menopause. (emphasis added)

227. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in an advertisement for Defendant HRC Medical's BHRT:

Bioidentical hormones are completely safe. Now, what that means is that the side effects, in men, there are no side effects to testosterone. Women, it is possible if you the dose a little bit too high or if they're very sensitive to it, they may get a little bit of a shadow. All that means is we just cut back on the testosterone a little bit. (emphasis added)

228. Given that the formulation of Defendant HRC Medical's BHRT has not changed, Defendant Dan Hale and Defendant HRC Medical's statements cannot be reconciled against the list of potential side effects that Defendant HRC Medical inconspicuously, incompletely, and, in many places, inaccurately posts on remote portions of its webpage, www.hrcmedical.com.

229. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT has no or limited side effects or that its components have no, limited, or minimal side effects.

230. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT has no, limited, or minimal side effects.

EXPRESS CLAIMS THAT DEFENDANT HRC MEDICAL'S BHRT DOES NOT HAVE SIDE EFFECTS ASSOCIATED WITH TRADITIONAL HRT

231. Defendants have all falsely, deceptively, and/or without adequate substantiation claimed that Defendant HRC Medical's BHRT is safer than and does not have the side effects and risks associated with traditional hormone replacement therapy.

232. On a brochure given to prospective consumers in Tennessee, Defendant HRC Medical and Defendant HRC Management Midwest have stated the following, in relevant part, as excerpted below in quotes and in Figure 16:

Perhaps most importantly, since it is naturally derived, it does not carry the risks associated with synthetic treatments. (emphasis added)

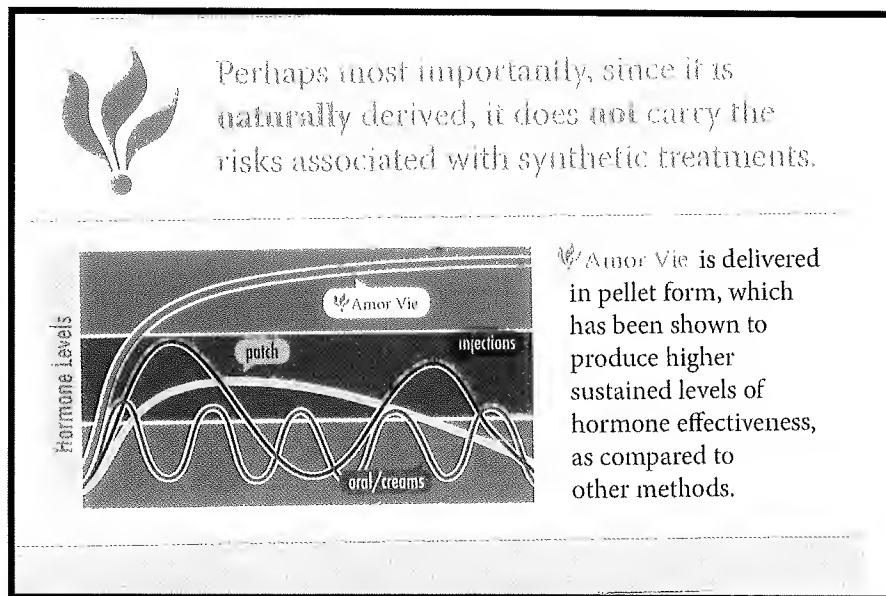


Fig. 16 (Not to Scale)

233. In its Welcome Packet given to consumers in Tennessee, Defendant HRC Medical has stated the following, in relevant part:

Our pellets are identical to the hormones created naturally by the body when we were in our prime. *They are NOT synthetic and therefore do not create the side*

effects often associated with synthetic versions of these hormones found in oral, injectable, or forms of those absorbed through the skin in gels, oils or patches. (emphasis added)

234. Defendant HRC Medical has stated on its website, www.hrcmedical.com, the following, in relevant part:

The sex stimulating hormones we successfully replace are Testosterone, Estrogen, and Progesterone. *Amor Vie therapy is safe and is not associated with the risk [sic] and side effects of synthetic hormones.* (emphasis added)

235. On January 24, 2012, and April 5, 2012, Defendant HRC Medical stated the following on its Facebook page for its Nashville office:

Bio-Identical Pellet Hormones are made from a plant source, usually yams or soy. *These types of hormones do not have the side effects seen in synthetic hormone replacement.* (emphasis added)

236. On March 8, 2012, Defendant Dan Hale, on behalf of Defendant HRC Medical, stated the following on its Facebook page for its Knoxville office:

Natural hormones as we had when we were 25 do not have the side effects associated with synthetics. (emphasis added)

237. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT:

Bio-identical hormones are different than the traditional because bio-identical means biologically identical. That means that they are the same as the hormones you had when you were twenty years old. I try to visualize it this way. If this is your hormones I had when I was twenty [holds palm up facing sideways] then this [sic] is the hormones that we're putting in [holds up other hand and presses palms together]. These are biologically identical. That means they're different than the synthetic. The synthetic kinds of hormones are the ones that cause breast cancer, cervical cancer, heart disease, blood clots. Go to the website and type in 'Women's Health Initiative' study. You can read about that. You can find out the bad things made from horse urine. That's conjugated estrogen. The bio-identical hormones do not. They are probably are somewhat protective. (emphasis added)

238. Defendant Dan Hale, on behalf of Defendant HRC Medical, has also stated the following in advertisements for Defendant HRC Medical's BHRT:

People are wanting to get away from the synthetic hormones made from horse urine, made from the urine of pregnant mares. *Those are the things that have a lot of side effects.* They're wanting the kind of natural hormones you had when you were 20 years old, so a lot of people are seeking this therapy. I think it's going to continue to grow because, like Oprah, she had it on her television program. We know that Suzanne Somers has written 3 books on it. *Go on the Internet and read about bio-identical hormones and you'll see that there's a lot of information out there and all of it is positive. You're not going to see anything where it says the bio-identical hormones causes anything bad at all cause it's just not there. If there's anything bad about something, it'll show up on the Internet as you know. You're not going to find it because bio-identical hormones are the same kind of hormones you had when you were twenty years old.* (emphasis added)

239. In an advertisement with WSMV, Defendant HRC Medical, through Jennifer Herron speaking on behalf of Defendant HRC Medical, stated the following, in relevant part:

JENNIFER HERRON: *As far as side effects, Dr. Hale says that they are minimal compared to traditional hormone treatments.* Acne and extra hair growth does [sic] occur in some patients. But Dr. Hale says that a tweak in the hormone levels will solve that. (emphasis added)

240. On Defendant HRC Medical's website, www.hrcmedical.com, Defendant HRC Medical has stated the following:

But the key to replace them (estradiol, progesterone and testosterone) with hormones that are a duplicate of those we had when we were 25 years old. *We have learned from years of using synthetic hormones (Premarin, Provera, and Prempro) that these can cause many negative side effects. In a study involving 16,608 women, the Women's Health Initiative Trial, it was shown that using these synthetic hormones [sic] women are more likely to develop breast cancer, heart attacks, strokes and blood clots. Natural hormones as we had when we were 25 do not have the side effects associated with synthetics.* (emphasis added)

241. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part:

Bio-identical Hormones are different than the usual synthetic hormones, the most common being Premarin, conjugated estrogen. *This is the synthetic estrogen used in the Women's Health Initiative Study showing an increase in breast cancer, cervical cancer, strokes and heart attacks. This study involved over 16,000 women. . . . Bio-Identical Pellet Hormones are made from a plant source, usually yams or soy. These types of hormones do not have the same side effects seen in synthetic hormone replacement.* (emphasis added)

242. Defendant HRC Medical has stated the following on its website, www.hrcmedical.com, in relevant part:

Our Amor Vie™ hormones, naturally derived from plant extracts, are a molecular match to what the body produces. *This benefits us because they are recognized by our bodies as natural and do not have the side-effects associated with synthetics.* (emphasis added)

243. On July 9, 2011, Defendant HRC Medical stated the following on its Facebook page for its Nashville office:

HRT (ERT estrogen replacement therapy) scares most women because they have the impression that *all estrogens are dangerous. Bio-Identical Hormone Replacement Therapy is just the opposite. . . . BHRT prevents disease while relieving symptoms.* (emphasis added)

244. More recently, Defendant HRC Medical has stated the following on its website, www.hrcmedical.com, in relevant part:

Like virtually every other medical treatment, procedure or prescription medication, that is designed to improve your overall well being, bioavailable Natural Hormone Replacement Therapy (bioNHRT) affects how your body functions so you can realize improvement in the areas desired and may have a few side effects or carry some small risks for a very small percentage of patients. You need to have a thorough understanding of them to evaluate the therapy for yourself. *But, unlike many other medical treatments, procedure, or prescription medication, the Natural Bio-Available Hormones used in HRC's AMORE [sic] VIE therapy are naturally derived (from the Yam plant). Being naturally derived, they work almost identically to those hormones already existing in the human body without the introduction of any synthetic matter that greater change the risk factor evaluation. . . . It is important to note that almost all of the side effects that might be experienced can be adjusted dosing related in that if side effects are felt a simple reduction in dosing will generally reverse the affect [sic].* (emphasis added)

245. Defendant Don Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in an advertisement aired on WSMV:

No one can find any evidence that having your hormone levels raised back like they were in their [sic] youth can hurt you in any way if it's done with natural hormones as opposed to synthetic hormones. (emphasis added)

246. As part of Defendant HRC Medical's effort to make superiority claims over traditional HRT, Defendant HRC Medical, and Defendant Dan Hale, on behalf of Defendant HRC Medical, have falsely, deceptively, and/or without adequate substantiation asserted that the human body is not able to process conjugated estrogens made from equine urine and have suggested that the risks associated with traditional HRT products stem from the body's purported inability to process products derived from horse urine.

247. For example, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements for Defendant HRC Medical's BHRT:

Our bodies are not made to metabolize horse urine, but they are made to metabolize natural hormones. So they – so there are actually no health risks that we've ever been able to determine with the bio-identical hormones. (emphasis added)

248. Defendant Dan Hale, in advertisements for Defendant HRC Medical's BHRT, has stated the following, in relevant part:

Our bodies are not made to process horse urine. (emphasis added)

249. Elsewhere, Defendant HRC Medical has stated the following in an advertisement for its BHRT:

The reason our bodies cannot eliminate the unnatural chemicals found in horse urine is because we do not have the enzymes a horse has. But we do have the necessary enzymes to breakdown natural bio-available estradiol. (emphasis added)

250. On June 16, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook account for the Memphis office:

Pellet Hormones are made from a plant source, usually yams or soy. *These types of hormones do not have the side effects seen in synthetic hormone replacement.* The Pellets are Testosterone and Estradiol.

251. Likewise, on June 10, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook page for the Memphis office:

The AMOR VIE Therapy uses "Bio Natural/Bio Available" Hormone replacement compounded to mirror the hormones naturally produced in the human body. This eliminates the risk of synthetic hormones that have received much attention over the last several decades. The Hormone formulations have been in use since the 1930s.

252. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT is superior to traditional hormone replacement therapy and does not have the potential side effects associated with commercial pharmaceutical hormone replacement therapy.

253. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT is superior to traditional hormone replacement therapy and does not have the potential side effects associated with commercial pharmaceutical hormone replacement therapy.

EXPRESS ANTI-AGING CLAIMS

254. Defendant HRC Management Midwest, Defendant HRC Medical, Defendant Dan Hale, and others on behalf of Defendant HRC Medical have made a series of claims that Defendant HRC Medical's BHRT can be used to prevent, treat, or cure diseases or conditions associated with aging, when those claims were false, deceptive, and/or not adequately substantiated.

255. Essentially, Defendants advance the following fallacy of logic in their advertising: People in their twenties and thirties generally have higher hormone levels than they do with advanced age and typically do not have diseases like cancer, heart disease, strokes, and other diseases associated with aging. If you restore a person's hormone levels to the levels he or she had when he or she was twenty or thirty, then the person will be protected from cancer, heart disease, strokes, and other diseases associated with aging.

256. In an advertising piece authored by Defendant Dan Hale and posted on Defendant HRC Medical Center's website, www.hrcmedical.com, Defendant Dan Hale states in relevant part:

One author said, 'Losing our hormones is like a vacuum sweeper sucking the life right out of you.' But the good news is that we do not have to tolerate the ravages of loss of hormones. These hormones can be replaced by natural hormones that are exactly like the hormones you had when you were 25. *You can live a longer and healthier life.* We all want our health to last as long as our life. Please let us help at HRC Medical. Dr. Dan. (emphasis added)

257. On January 25, 2012, March 5, 2012, March 21, 2012, and April 2, 2012, Defendant HRC Medical stated the following on its Facebook page for the Nashville office:

Did you know? Estrogen is a female hormone produced by the ovaries until menopause. Low estrogen contributes to osteoporosis, arteriosclerosis, hot flashes, poor memory, and dry vaginal mucosa. *Estrogen's anti-aging benefits include stronger bones, decreased heart disease and strokes, thicker skin and increased lifespan.* (emphasis added)

258. Defendant Dan Hale has stated on Defendant HRC Medical's website:

"We all have to go to our reward eventually, *but we can slow down the dying process until that day comes.*" (emphasis added)

259. Similarly, Defendant HRC Medical's sales materials have stated the following, in relevant part:

You have made the right decision toward improving your quality of life by restoring, rebalancing and maintaining your essential hormone levels to achieve optimal results,

be 'symptom free' and to love life again. *Aging doesn't have to mean 'getting old.'* (emphasis added)

260. Prior television commercials for Defendant HRC Medical's BHRT that aired in Tennessee stated, "*It may not be the fountain of youth, but it's pretty close.*" (emphasis added)

261. Defendant HRC Medical has stated in television advertisements on WKRN, Nashville's ABC affiliate, the following, in relevant part:

Turn back the hands of time with Amor Vie Therapy. (emphasis added)

262. Other television commercials for Defendant HRC Medical's BHRT state that the therapy allows consumers to "reverse the numbers" in his or her age. For example, "42 becomes 24."

263. In advertisements for Defendant HRC Medical's BHRT, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part:

There's no difference in someone whose 40 and someone whose 20 if we can balance their hormones. (emphasis added)

264. Defendant HRC Medical stated in a press release for Defendant HRC Medical's BHRT in which Defendant Dan Hale and Defendant Don Hale are quoted, the following, in relevant part:

In the process of aging, many things start to decline, our health becomes iffy, energy dissipates, we feel weak and tired, headaches are more prevalent and sadly, our sex drive goes out the window. The good news is that there is help! International talk show host, Oprah, has provided the platform for Suzanne Somers to share the miraculous effects of what she considers a natural cure for aging. Bioidentical Hormone Replacement Therapy has been changing the lives of thousands and its happening at HRC Medical Center in Nashville. Pioneers in the industry of health and beauty rejuvenation, HRC Medical Centers, under the helm of brothers Don Hale & Dr. Dan Hale, have treated thousands of patients to restore their health and vitality through bioidentical hormone replacement. . . . Founded in 2005, by Dr. Dan Hale and Don Hale, HRC Medical Center provides the latest in anti-aging techniques. (emphasis added)

265. On Defendant HRC Medical's website, Defendant Dan Hale stated the following:

Bio-Identical Hormone Replacement

Written by: Dr. Dan Hale

Medical Director HRC Knoxville

Hormones control every system of the body. *Hormone replacement is a treatment of prevention of disease instead of cure. Most diseases....heart attacks, strokes, arthritis, loss of sex drive, obesity, breast and cervical cancers, fatigue, poor sleep....occur after age 40. 98% of the patients over 40 have low hormones. . . . Bio-Identical Hormone Replacement Therapy is just the opposite. . . . BHRT prevents disease while relieving symptoms.* (emphasis added)

266. On July 19, 2011, Defendant HRC Medical stated the following on its Facebook page for its Knoxville office:

Did you know that hormones control every system of the body? *Hormone replacement is a treatment of prevention of disease instead of cure. Most diseases . . . [h]eart attacks, strokes, arthritis, loss of sex drive, obesity, breast and cervical cancers, fatigue, poor sleep . . . occur after age 40. 98% of the patients over 40 have low hormones. Let HRC Knoxville help balance your life. Contact our office @ (865) 670-0039 with any questions or to schedule your free consultation today.* (emphasis added)

267. In a brochure handed out to potential consumers of Defendant HRC Medical's BHRT, created by Defendant HRC Medical, Defendant HRC Medical has stated the following, in relevant part:

Estrogen's anti-aging benefits include stronger bones, decreased heart disease and strokes, thicker skin and increased lifespan. . . . Anti-aging benefits of testosterone therapy are improved mood and feeling of well being, decreased fatigue, more red blood cells, reduced cholesterol, stronger bones, increased sex drive, and sexual potency. . . . The anti-aging benefits [of progesterone] include reduction of stress and arthritic inflammation, maintenance of memory, improved mood, enhanced well-being, and improved sleep. (emphasis added)

268. On Defendant HRC Medical's Facebook page for its Nashville office, Defendant HRC Medical has stated the following:

You can't turn back the clock. But you can wind it up again. Bonnie Prudden. Another well put quote that reminded us, here at HRC, of what we hear daily from our awesome patients. *Feeling awful & out of whack doesn't have to be part of 'growing older'.* A 20 min consultation & some blood work is all it takes to get the ball rolling towards a better living! Call us TODAY!!! (emphasis added)

269. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated in promotional pieces for Defendant HRC Medical's BHRT the following, in relevant part:

When we see a dead fish in the river and look for the source of the problem. We need to do the same thing in medicine. Doctors need to be asking the question, 'Why did this patient get sick? Why did he have a heart attack at 48 or 58? What could have been done to prevent this from happening? *We need to treat diseases before they occur. I will discuss next week the first step in prevention. It begins with hormone balance.* Dr. Dan. (emphasis added)

270. On March 14, 2012, Defendant HRC Medical stated the following on its Facebook page for its Knoxville office, in relevant part:

The benefits are definitely helpful to women who are undergoing perimenopause period. *It is true that aging cannot be prevented but you can always do something to stay young and healthy if you want to.* (emphasis added)

271. On June 18, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook page for the Memphis office:

The benefits are definitely helpful to women who are undergoing perimenopause period. It is true that aging cannot be prevented but you can always do something to stay young and healthy if you want to. If you have not scheduled your FREE consultation yet, give us a call!

272. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT acts as a general preventative or treatment of aging itself, diseases or conditions associated with aging, or diseases and conditions that are more prevalent among older individuals.

273. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT acts as a general preventative or treatment of aging itself, diseases and conditions associated with aging, or diseases and conditions that are more prevalent among older individuals.

EXPRESS CARDIOVASCULAR BENEFIT CLAIMS

274. The heart, blood, and blood vessels are the principal components of the cardiovascular system in the human body. Cardiovascular disease is the broad term for a class of diseases that concern the heart or blood vessels.

275. There is some evidence *to suggest* that estrogen-only therapy may play a protective role against heart disease *if* it is administered before the onset of heart disease. These studies, however, did not evaluate the effect of estrogen with mega-doses of testosterone, such as those found in Defendant HRC Medical's BHRT, nor the high estradiol dosages that Defendant HRC Medical, routinely gives with its BHRT.

276. Defendant HRC Management Midwest, Defendant HRC Medical and Defendant Dan Hale, on behalf of Defendant HRC Medical, have broadly claimed that Defendant HRC Medical's BHRT protects against various cardiovascular problems when those claims were false, deceptive, and/or unsubstantiated.

277. As an example, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in an advertisement for Defendant HRC Medical's BHRT on WSMV, in relevant part:

INTERVIEWER: Can you talk about that? Is it safe?

DAN HALE: I'm glad you asked that question. *So many people that they think that aw, it could cause heart attacks, strokes, blood clots, but every time they do those kind of studies they're talking about the synthetic kind. Every study done, there's many,*

many hundreds of studies that is [sic] out there that show hormones actually protect it, if it's the kind we had when we were 25 years old. (emphasis added)

278. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in relevant part, in advertisements for Defendant HRC Medical's BHRT, in relevant part:

We know there's been a lot of studies done, some major, major studies like the Women's Health Initiative trial showed that the synthetic hormones can also cause damage because we know there's a higher incidence of breast cancer, cervical cancer, blood clots, heart attacks, and strokes with the synthetic, but bioidentical makes them biologically identical, in other words it is you, so it's not something foreign to our body. (emphasis added)

279. On another occasion, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in an advertisement for Defendant HRC Medical's BHRT on WSMV, in relevant part:

DAN HALE: As a matter of fact there are a lot of studies that they've even shown that we're more protected from coronary heart disease, heart attacks, strokes, blood clots and even protected against cancer if our hormones are in balance. (emphasis added)

280. On January 23, 2011, on its Facebook page for the Nashville office, Defendant HRC Medical stated the following, in advertisements for its BHRT, in relevant part:

Here are a few benefits outside of symptom relief. In addition to the extensive symptom relief our patients experience consciously, there are multiple benefits that occur "under the radar" such as mitigation of bone loss, cholesterol reduction and cardiovascular benefits. (emphasis added)

281. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, about Defendant HRC Medical's BHRT, in relevant part:

Heart attacks . . . Bio-Identical Hormones are most likely protective . . . Synthetic hormones have many bad effects – 29% increase in heart disease . . . 40% increase in embolic diseases (blood clots) . . . HRT (ERT....estrogen replacement therapy) scares most women because they have the impression that all estrogens are dangerous. Bio-Identical Hormone Replacement is just the opposite . . . BHRT prevents disease while relieving symptoms. (emphasis added)

282. Defendant HRC Medical has stated that its BHRT helps with symptom relief including for:

[E]pisodes of rapid heartbeat, with or without anxiety. Out of nowhere my heart starts beating out of my chest.

283. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following about Defendant HRC Medical's BHRT:

Hormone replacement is a treatment of prevention instead of cure. . . .*Congestive heart failure - Testosterone strengthens the heart muscle.* (emphasis added)

284. On June 3, 2012, and June 23, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following consumer testimonial on their Facebook page for the Memphis office:

After 7 years of fighting the expected discomforts and changes of aging and menopause, I simply could not bare [sic] the creams and pills, and "snake oil" remedies anymore. I just wasn't me. I felt so tired all the time, but still tried to fight my weight by exercising after work and eating right. The weight continued to [increase] along with the belly fat. I was beyond unhappy. I was fighting a losing battle. When my libido was gone, I was done! So was my husband. So after hearing from friends about their great experience at HRC I decided to give it a try. And I am so glad I did and so is my husband! After being shown exactly how bad my hormone levels were, I happily had my first implant. . . . *My heart flutters were much less frequent*, and I was actually using my reading glasses less. It was hard to believe. I felt calm, but energetic, ready for walking anytime and staying up later. I could get through the 2 p.m. slump at work with no problem there was no slump! My craving for food was diminished greatly, and I could tell I was not on edge or feeling anxiety.

I was just happier! So was my husband. On the flip side I could tell that my voice was a bit raspier and my hair was oilier, and my cheeks looked flush and rosy throughout the day, but those things will either pass in time or be of no consequence.

I cannot believe the enormous change I felt in such a few days!! I can only think that the days ahead are going to be better and better. I feel so young again! And the things my balanced body are doing for me INSIDE that I cannot see if a whole exciting story in itself. The staff and nurses and doctors are wonderful and so informative. Their use of only the finest products and labs and pharmacies is impressive. I have recommended HRC to EVERYONE who will listen. And many around me are just watching so let them watch! Thank you, HRC, for giving me my (and my husband's) life back! Cindy - Patient

285. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT has cardiovascular benefits and can be used to treat, prevent, or cure cardiovascular disease.

286. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT has cardiovascular benefits or can be used to treat, prevent, or cure cardiovascular disease.

EXPRESS CHOLESTEROL REDUCTION OR TREATMENT CLAIMS

287. Cholesterol and triglycerides are two forms of fat that circulate in the bloodstream. Cholesterol, in moderate levels, helps to build and maintain key structures within cells and maintain hormones. Generally speaking, cholesterol comes in two forms, low density lipoprotein (LDL) and high density lipoprotein (HDL).

288. In the bloodstream, "bad" cholesterol is carried in LDL and "good" cholesterol is carried in HDL. Elevated LDL levels have been strongly associated with an increased risk of heart attacks and strokes. Triglycerides, which are chains of high-energy fatty acids, provide a substantial portion of the energy an individual's tissues need to function. But when the levels of cholesterol or triglycerides are too high, the risk of developing cardiovascular disease is greatly increased.

289. Defendant HRC Medical, and Defendant Dan Hale, on behalf of Defendant HRC Medical, have made repeated claims that Defendant HRC Medical's BHRT reduces cholesterol or that it can be used to prevent, treat, or cure high cholesterol when those statements were false, deceptive, and/or not adequately substantiated.

290. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in relevant part in an advertisement for Defendant HRC Medical BHRT on WSMV, in relevant part:

VOICE OVER: Dr. Hale says that there are other health benefits with hormone replacement therapy.

DAN HALE: *The average cholesterol reduction is 50 points. I've seen a 20 point reduction on nothing but just the hormones. Blood pressure. You know I was on blood pressure medicine—don't take it anymore at all. Some people still have to be on it but at a reduced level. . . .* (emphasis added)

291. Defendant HRC Medical has stated the following in advertisements about its BHRT:

The Benefits Beyond Feeling Better – Most everyone will receive relief of their symptoms: tiredness, depression, poor sleep, erectile dysfunction, vaginal dryness, hot flashes, and loss of muscle tone. But there are many benefits beyond just feeling better. . . . *Many times blood pressure is lowered as well as cholesterol.* Many studies show positive results of less strokes, ovarian cancer, and heart disease. (emphasis added)

292. Defendant HRC Medical has stated the following on its website, www.hrcmedical.com, in relevant part:

Amor Vie™ therapy is an effective way to restore one's health *and alleviate the symptoms related to hormonal imbalance and deficiencies.*

Symptoms that indicate a lack of or imbalance of Estrogen, Testosterone, or Progesterone . . . *High Cholesterol.* (emphasis added)

293. In an advertising pamphlet for Defendant HRC Medical's BHRT, Defendant HRC Medical states the following, in relevant part:

Hormone deficiency symptoms we don't have to live with: . . . *high cholesterol.* (emphasis added)

294. Defendant HRC Medical states the following in relevant part in an advertisement for Defendant HRC Medical's BHRT, in relevant part:

Bioidentical hormones are providing spectacular results for women of all ages. They can be beneficial for treating thyroid conditions and lowering cholesterol levels and even improving the appearance of skin and hair. (emphasis added)

295. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT reduces ones cholesterol or can be used to treat, prevent, or cure high cholesterol.

296. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT reduces cholesterol or that Defendant HRC Medical's BHRT can be used to treat, prevent or cure high cholesterol.

EXPRESS ALZHEIMER'S DISEASE AND MEMORY LOSS CLAIMS

297. Alzheimer's Disease is a disease that causes brain cells to degenerate and die, causing a steady decline in memory and mental function.

298. Defendant HRC Management Midwest, Defendant HRC Medical, and Defendant Dan Hale, on behalf of Defendant HRC Medical, have claimed that Defendant HRC Medical's BHRT treats, prevents, or cures Alzheimer's Disease and memory loss generally when those claims were false, deceptive, and/or not adequately substantiated.

299. Defendant HRC Medical has stated the following, in relevant part:

Hormones that are not balanced leads [sic] to breast cancer, ovarian cancer and Alzheimer's. (emphasis added)

300. In an advertisement on WSMV, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part:

Without hormones, we develop Alzheimer's. . . . So all of those things are caused because of loss of hormones and we replace those hormones with natural hormones. (emphasis added)

301. Defendant Dan Hale, on behalf of Defendant HRC Medical, stated the following in relevant part:

Let's talk about memory loss. This seems to be such a big, big problem when people lose their hormones. I remember my daughter, she's a pharmacist. She had a hysterectomy, which is surgical menopause. She just couldn't remember things at all. As a pharmacist, she said that she'll be trying to fill a prescription and she was thinking, "What is this medicine for?" That's a bad thing for a pharmacist. We put the bioidentical hormones in her and I think she said 'two weeks' in two weeks time she said my memory came back just as fresh as it was years ago. So many people will go to the store and they'll say why [sic] I am doing in this store? Or they can't remember where they put their car keys or can't remember people's names [unintelligible]. So that's hormones so remember there are more receptor sites for hormones in the brain than in any other part of the body. So we know that hormones affect her thinking and her memory. So memory loss it can be helped with the bioidentical hormones. (emphasis added)

302. Defendant Dan Hale, on behalf of Defendant HRC Medical, stated the following, in relevant part:

With loss of hormones there is an increase in coronary artery disease and Alzheimer's. One author said, "Losing our hormones is like a vacuum sweeper sucking the life right out of you." But the good news is that we do not have to tolerate the ravages of loss of hormones. These hormones can be replaced by natural hormones that are exactly like the hormones you had when you were 25. You can live a longer and healthier life. We all want our health to last as long as our life. Please let us help at HRC Medical. Dr. Dan. (emphasis added)

303. On September 9, 2011, Defendant HRC Medical stated the following, on its Facebook page for its Nashville office, in relevant part:

SYMPTOMS OF HORMONE IMBALANCE: - Memory Loss . . . If you are tired of suffering from any of these symptoms give HRC Medical a call today and schedule your free 20 minute consultation. (emphasis added)

304. On September 8, 2011, Defendant HRC Medical stated the following, on its Facebook page for its Nashville office, in relevant part:

Here is one of our Frequently Asked Questions: What should I expect after the procedure? Within 10 to 14 days you should begin feeling the relief of some of your symptoms. In 2 to 3 weeks you should see a marked difference . . . more energy, increased sex drive, better rest, better memory, better mood, and better able [sic] to handle stress. (emphasis added)

305. On August 5, 2012, Defendant HRC Medical and Defendant HRC Management Midwest stated the following, on their Facebook account for the Memphis office, in relevant part:

Hormones enter into all 100,000,000,000,000 (that's 100 trillion) cells in our body. Inside the cells hormones start a cascade of reactions which causes the "target cell" to perform the intended functions, to produce energy, *to aid in memory*, to increase the sex drive, to increase muscle development, to build bones, etc. *Without this action by hormones these functions gradually decline.* That is called menopause in women and andropause in men. When hormones begin to decline this is a sign of the beginning of the dying process. *Our bodies cannot function as well (cannot function at all) without hormones.* (emphasis added)

306. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent or cure Alzheimer's Disease or memory loss generally.

307. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure Alzheimer's Disease or memory loss generally.

EXPRESS DIABETES CLAIMS

308. Diabetes refers to a group of diseases that affect how one's body uses blood glucose ("blood sugar"). Glucose is an important source of energy for the cells that make up one's muscles, tissues, and organs. Regardless of the type of diabetes, it means that the individual has too much glucose in his or her blood, although the reasons may differ. Too much glucose in the blood can lead to serious health problems.

309. Defendant HRC Medical and Defendant Dan Hale have claimed that Defendant HRC Medical's BHRT prevents, treats, or cures diabetes when those claims were false, deceptive, and/or not adequately substantiated.

310. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part:

Diabetes – Many are able to reduce or even discontinue their diabetes medications. (emphasis added)

311. Defendant HRC Medical has stated the following about its BHRT, in relevant part:

Many can reduce their use of oral anti-diabetic medications. (emphasis added)

312. Defendant HRC Medical has stated the following, in relevant part:

Many type 2 diabetics are able to decrease or discontinue their medicines and control their blood sugars with diet and exercise alone. (emphasis added)

313. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated on multiple occasions that Defendant HRC Medical's BHRT can prevent the onset of diabetes.

314. For example, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following:

Last week we learned that hormones can actually change our genes, which changes our chances of developing . . . diabetes . . . How does this work? Hormones enter into all 100,000,000,000 (that's 100 trillion) cells in our body. Inside the cells hormones start a cascade of reactions which causes the "target cell" to perform the intended functions, to produce energy, to aid in memory, to increase the sex drive, to increase muscle development, to build bones, etc. Without this action by hormones these functions gradually decline . . . Our bodies cannot function as well (cannot function at all) without hormones. That is why it is crucial to replace these lost hormones. But the key is to replace them (estradiol, progesterone, and testosterone) with hormones that are an exact duplicate of those we had when we were 25 year [sic] old. (emphasis added)

315. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure diabetes.

316. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure diabetes.

**EXPRESS DEPRESSION OR ANTI-DEPRESSANT SUPERIORITY,
EFFICACY, OR EQUIVALENCY CLAIMS**

317. Clinical depression is a mood disorder characterized by long periods of feelings of sadness, loss, anger, or frustration.

318. Defendant HRC Management Midwest, Defendant HRC Medical, Defendant Dan Hale, on behalf of Defendant HRC Medical, have stated that Defendant HRC Medical's BHRT can be used to treat, prevent or cure depression and that it operates as a safer alternative to FDA-approved anti-depressants with the same efficacy when those claims were false, deceptive, and/or not adequately substantiated.

319. For example, Defendant HRC Medical has stated the following on its website:

The Benefits Beyond Feeling Better *Most everyone will receive relief of their symptoms: . . . depression . . .* (emphasis added)

320. Defendant HRC Medical has also stated the following, in advertisements about its BHRT, in relevant part:

Last year there were 118,000,000 prescriptions written for anti-depressants. This does not have to happen. When your hormones are balanced you will sleep much better, have an active sex life and be able to get off your anti-depressants. (emphasis added)

321. Elsewhere, Defendant HRC Medical has stated in advertisements for its BHRT the following on its website, in relevant part:

Inadequate hormone levels can attribute to . . . even depression In many cases these negative effects are ignored or discounted by the traditional medicine. Some look at these symptoms as being part of the aging process and suffering individuals are told to "deal with it," "it will pass" or "this comes with getting older." The good news is that in most cases these conditions can be treated through use of our exclusive bio-natural Amor Vie Therapy. . . We do not only relieve our patients [sic] symptoms, we treat the actual cause of them. (emphasis added)

322. Defendant HRC Medical has also stated the following, about its BHRT in advertisements, in relevant part:

Amor Vie™ therapy is an effective way to restore ones [sic] health and alleviate the symptoms related to hormonal imbalance and deficiencies. Symptoms that indicate a lack of or imbalance of Estrogen, Testosterone, or Progesterone Symptoms Affecting Both Males & Females . . . Depression . . . (emphasis added)

323. Defendant HRC Medical has also stated the following, about its BHRT in its advertisements, in relevant part:

If you're suffering from any of the symptoms you see on the screen [[Screen Shot Says] *Symptoms of Hormone Imbalance Depression . . .*] we urge you to take the Amor Vie test today and find out if Amor Vie therapy is right for you. . . . *If you do have a hormone imbalance, HRC will design a program specifically for you based on your symptoms, your body and your needs. So don't settle for suffering, call HRC Medical today!* (emphasis added)

324. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in advertisements for Defendant HRC Medical's BHRT, in relevant part:

It's wonderful to get rid of the hot flashes, night sweats, the restless leg syndrome, the depression, it's wonderful to get rid of those things, but we also need to think about our overall health with the hormones for years and years to come. (emphasis added)

325. Defendant Dan Hale, on behalf of Defendant HRC Medical, and Defendant HRC Medical has stated the following, in advertisements about Defendant HRC Medical's BHRT, in relevant part:

The second hormone women loose [sic] is progesterone. This is seen as a change in the menstrual cycle, sleep disturbance, agitation, and *depression*. This is sad to see because often the patient will see their primary care doctor and after a short conversation will be told, 'I am going to put you on an anti-depressant. This will help with your anxiety and help you cope.' This is so sad because you do not have a 'Prozac deficiency', you have a hormone deficiency. There are many side effects to these medications including: weight gain, markedly decreased sex drive and an inability to have an orgasm. Last year there were 118,000,000 prescriptions written for anti-depressants. This does not have to happen. *When your hormones are*

balanced you will sleep much better, have an active sex life and be able to get off your anti-depressants. (emphasis added)

326. Defendant HRC Medical has stated the following, about its BHRT, in relevant part:

Natural hormones as we had when we were 25 do not have the side effects associated with synthetics. Many studies have been done showing the beneficial effects of replacing these hormones as they decline. . . . *Many studies can be found on medical web sites showing there is less . . . depression . . .* (emphasis added)

327. In advertisements for its BHRT, Defendant HRC Medical has used consumer testimonials to assert that its BHRT can be used to treat depression. For example, consumers in ads for Defendant HRC Medical's BHRT have stated the following:

Testimonial 1: Before I came to HRC Medical, *I was very depressed.* I was very unhappy. I was crabby. *I was not really looking forward to the rest of my life because I really felt like I lived my life. Everything was done.*

Testimonial 2: I was sitting on my couch one day doing nothing and I had been doing nothing for months and I felt miserable, I couldn't sleep.

Testimonial 3: People used to call me "sunshine" and for a while there I lost it, *the sun had kind of set.* I didn't have me.

Testimonial 4: I didn't want to be around any other people. I didn't want to be around my immediate family half of the time. *I just wanted to be alone.*

Testimonial 5: I just wasn't happy. Things that made me happy didn't work. Didn't seem to help by exercise or by visiting my friends, it still didn't help. I was just very unhappy. I was sad, I felt old and tired.

Testimonial 6: *My life had become a dark and lonely place.*

These are heartbreaking stories. Fortunately, the solution is right here. Amor Vie therapy from HRC.

Testimonial 1: Since I started the Amor Vie hormone therapy, every day is like a vacation. That's a good day.

Testimonial 2: Now that I have Amor Vie therapy, my life is a ball and most people that know me know that something really exciting has happened.

Testimonial 3: Now the sun is rising again. I actually do get people that call me "sunshine" again. I even have a friend that calls me champagne. She says, "You bubble over." I love that.

Testimonial 4: I get up in the mornings, I take a shower and I'm on with my day and I accomplish so much during the day and have a smile on my face when my children arrive home from school. (emphasis added)

328. On June 26, 2012, and July 25, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook account for the Memphis office:

Hormone deficiencies and imbalances can have a severe negative impact on daily lifestyles in both men and women. Inadequate hormone levels can attribute to loss of energy, low sex drive, sexual dysfunction, weight gain, hot flashes and night sweats, loss of lean muscle, *even depression and mood swings*, to mention only a few. In many cases these negative effects are ignored or discounted by the [sic] traditional medicine. Some look at these symptoms as being part of the aging process and suffering individuals are told to "deal with it", "it will pass" or "this comes with getting older". *The good news that in most cases these conditions can be treated through use of our exclusive bio-natural Amor Vie® Therapy.* At HRC we achieve optimized hormone levels for our patients by restoring those levels back to that of their prime not just the levels for mid-life or senior adults. We are so confident that we can optimize an individual's hormone levels we offer a written guarantee. We do not only relieve our patients symptoms, we treat the actual cause of them. (emphasis added)

329. On July 9, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook account for the Memphis office:

Depression can be the result of any number of underlying causes ranging from clinical depression, to a chemical imbalance, to emotional trauma. Another possibility may be through the loss of hormones. For some, rebalancing their hormones may provide "light at the end of the tunnel". Call HRC Medical Center today to see if Amor Vie Therapy is right for you! (emphasis added)

330. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure depression or that it is superior to or as effective as pharmaceutical anti-depressants.


331. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT is superior to or as effective as pharmaceutical anti-depressants or that it can be used to, treat, prevent, or cure depression.

EXPRESS ATTENTION DEFICIT HYPERACTIVITY DISORDER CLAIMS

332. Attention Deficit Hyperactivity Disorder (ADHD) is a developmental disorder that most often manifests itself as hyperactivity and difficulty maintaining focus on a given task. It is diagnosed and studied mostly in children, but can also be a chronic condition that lasts into adulthood.

333. Defendant HRC Medical has claimed that its BHRT can be used to treat, prevent, or cure ADHD when those claims were false, deceptive, and/or not adequately substantiated.

334. Defendant HRC Medical has stated on its website, www.hrcmedical.com, excerpted below in Figure 17, that it can treat the following symptoms, including ADHD.



Symptoms Treated With Bio-Identical Hormones

The most common symptoms men and women face without sufficient hormones are:

• Poor sleep	• Loss of muscle tone
• Fatigue	• Decreased exercise
• Loss of sex drive	• Vaginal dryness
• Weight gain	• Depression
• Anxiety	• Stress
• ADHD	• Menstrual migraine headaches
• Hot flashes	• Night sweats
• Erectile dysfunction	• Osteoporosis
• Dry skin	• Diabetes mellitus
• Fibromyalgia	• Restless leg syndrome
• Palpitations	• Chronic fatigue syndrome
• Memory lapse	• Body-Joint Pains
• Painful intercourse	• Dry skin
• High cholesterol	• Hair loss
• Irritability	• Mood swings
• Poor concentration	• Self-confidence

Figure 17 (Not to Scale)

335. For example, Defendant HRC Medical has stated the following about its advertisements about Defendant HRC Medical's BHRT, in relevant part:

Some have been able to reduce their use of ADHD medications. For a time one may not have complete relief of their symptoms, but these disease processes improve with Bio-Identical Pellet Hormone Replacement Therapy. (emphasis added)

336. In advertisements for its BHRT, Defendant HRC Medical has listed ADHD as one of the conditions for which its BHRT provides relief.

337. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure ADHD.

338. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent or cure ADHD.

EXPRESS FIBROMYALGIA CLAIMS

339. Fibromyalgia is an ill-defined disorder loosely characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory, and mood issues.

340. Defendant HRC Medical and Defendant Dan Hale have claimed that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure fibromyalgia when those claims were false, deceptive, and/or not adequately substantiated.

341. For example, Defendant HRC Medical and Defendant Dan Hale, on behalf of Defendant HRC Medical, have stated the following, in relevant part:

Fibromyalgia – Progesterone relieves stress which is frequently the etiology of the inflammation of the muscles and ligaments and joints with fibromyalgia. (emphasis added)

342. Defendant HRC Medical has stated the following in a brochure advertising its BHRT, in relevant part:

Symptoms that indicate a lack or imbalance of Estrogen, Testosterone, or Progesterone: Symptoms Affecting Both Males and Females: . . . Fibromyalgia . . . Naturally derived Amor Vie will renew the hormone levels of your prime! . . . Amor Vie is delivered in pellet form, which has been shown to produce higher sustained levels of hormone effectiveness, as compared to other methods. Amor Vie is delivered in pellet form, which has been shown to produce higher sustained levels of hormone effectiveness, as compared to other methods. Rejoice! Amor Vie guarantees that your hormone levels will improve! HRC Medical patient sampling indicates that regular treatment provides a sustained hormone level, consistent with that of our prime. Our patients have self-reported life-changing IMPROVEMENTS in symptom relief. (emphasis added)

343. Defendant HRC Medical has stated the following, in relevant part:

Lack of progesterone has been shown to be a factor in causing fibromyalgia . . . You can prevent many of the negative consequences of the loss of hormones. Let HRC Medical help you. Dr. Dan Hale 10/10/11. (emphasis added)

344. On its Facebook page for its Nashville office, Defendant HRC Medical has stated the following on a post containing a link to consumer testimonials, in relevant part:

Do you suffer from Fibromyalgia? (emphasis added)

345. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure fibromyalgia.

346. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure fibromyalgia.

EXPRESS ARTHRITIS CLAIMS

347. Arthritis is a condition characterized by chronic joint pain and joint stiffness.

348. Defendant HRC Medical has claimed that its BHRT can be used to treat, prevent, or cure arthritis when those claims were false, deceptive, and/or not adequately substantiated.

349. On July 19, 2011, Defendant HRC Medical stated the following on its Facebook page for its Knoxville office, in relevant part:

Did you know that hormones control every system of the body. Hormone replacement is a treatment of prevention of disease instead of cure. *Most diseases . . . Heart attacks, strokes, arthritis, loss of sex drive, obesity, breast and cervical cancers, fatigue, poor sleep . . . occur after age 40. 98% of the patients over 40 have low hormones. Let HRC Knoxville help balance your life.* Contact our office @ (865) 670-0039 with any questions or to schedule your free consultation today. (emphasis added)

350. For example, on March 29, 2012, Defendant HRC Medical stated the following on its Facebook page for its Nashville office, in relevant part:

Joint & Body Aches, much like the effects of arthritis, is generally caused by inflammation of the affected area. Testosterone is a natural anti-inflammatory. As testosterone is replenished in our bodies it can have the effect of reducing the swelling that causes these aches. (emphasis added)

351. On November 11, 2011, Defendant HRC Medical stated the following on its Facebook page for its Nashville office, in relevant part:

Did you know that if you suffer from Arthritis, Hormone Replacement Therapy may help you? Testosterone functions as a natural anti-inflammatory. Call HRC Medical Center today to schedule your free consultation. (emphasis added)

352. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure arthritis.

353. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure arthritis.

EXPRESS RESTLESS LEG SYNDROME CLAIMS

354. Restless Leg Syndrome is a vaguely-defined disorder in which an individual feels a near-constant urge or need to move the legs to stop unpleasant sensations.

355. Defendant HRC Management Midwest, Defendant HRC Medical, and Defendant Dan Hale, on behalf of Defendant HRC Medical, have claimed that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure Restless Leg Syndrome when those claims were false, deceptive, and/or not adequately substantiated.

356. Defendant HRC Medical has stated the following in a brochure distributed to prospective customers in Tennessee about Defendant HRC Medical's BHRT:

Hormone deficiency symptoms we don't have to live with . . . restless leg syndrome
... (emphasis added)

357. Likewise, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

Many studies have been done showing the beneficial effects of replacing these hormones as they decline. As a matter of fact, these studies show that the earlier the better, even replacing diminishing hormones in perimenopause (the early stages of menopause) is more beneficial than waiting until menopause. Many studies can be found on medical web sites showing there is . . . a resolution of restless leg syndrome.
(emphasis added)

358. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

It's wonderful to get rid of the hot flashes, night sweats, the restless leg syndrome, the depression, it's wonderful to get rid of those things, but we also need to think about our overall health with the hormones for years and years to come. (emphasis added)

359. On its Facebook page for its Knoxville office, Defendant HRC Medical has stated the following about its BHRT, in relevant part:

Estradiol should relieve hot flashes, night sweats, vaginal dryness, dry skin, *helps with* sexual dysfunction, menstrual migraines, palpitations, *restless leg syndrome* and along with testosterone, reverses osteoporosis. (emphasis added)

360. Defendant HRC Medical has stated the following in advertisements for its BHRT, in relevant part:

[M]any of our patients with Restless Leg Syndrome have experienced relief of symptoms with the use of AMOR VIE Therapy allowing them to sleep more soundly at night. (emphasis added)

361. On October 3, 2011, on its Facebook page for its Nashville office, Defendant HRC Medical has stated the following about its BHRT, in relevant part:

Do you suffer from: *Restless Leg Syndrome . . . ?* These are the most common symptoms for people without sufficient hormones. Contact HRC Medical Center to schedule your free consultation. (emphasis added)

362. On June 11, 2012, Defendant HRC Medical and Defendant HRC Management Midwest, posted the following on their Facebook page for the Memphis office:

I began this program April 2011, a 48 year old woman losing sleep, *enduring restless legs nightly*, chronic fatigue, and constant night sweats. As a registered nurse I need my energy and sleep to be the best I can be to care for my patients. Additionally, my sex drive dipped to zero! *Until HRC I attributed all of this to mid life change. After 9 months of treatment I feel like a new woman. Middle aged women do not have to endure all those symptoms. My quality of life has improved greatly.* Thank you. Pam (emphasis added)

363. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure Restless Leg Syndrome.

364. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure Restless Leg Syndrome.

**EXPRESS HEAD HAIR GROWTH OR
INCREASED HEAD HAIR THICKNESS CLAIMS**

365. Baldness or thinning hair refers to excessive hair loss from one's scalp. Baldness or thinning hair occurs mostly in men, but can also be found in women.

366. Defendant Dan Hale, on behalf of Defendant HRC Medical, Defendant Don Hale, on behalf of Defendant HRC Medical, and Defendant HRC Medical have claimed that Defendant HRC Medical's BHRT will promote head hair growth or increased head hair thickness when those claims were false, deceptive, and/or not adequately substantiated.

367. Defendant HRC Medical's BHRT does not prevent, treat, or cure baldness or thinning hair—*rather Defendant HRC Medical's BHRT can cause it.*

368. Defendant HRC Medical has repeatedly stated that hair loss is a symptom of low hormone levels that can be alleviated by its BHRT.

369. Defendant HRC Medical has stated the following in brochures for its BHRT distributed in Tennessee to prospective consumers, in relevant part:

Hormone deficiency symptoms we don't have to live with: . . . hair loss . . . (emphasis added)

370. Defendant HRC Medical has stated the following on its Facebook page for its Nashville office regarding BHRT:

Do you suffer from: Restless Leg Syndrome, Chronic Fatigue Syndrome, Body-Joint Pains, Dry Skin, Hair Loss, or Mood Swings? These are the most common symptoms for people without sufficient hormones. Contact HRC Medical Center to schedule your free consultation. (emphasis added)

371. Defendant HRC Medical has featured consumer testimonials to advance this increased hair thickness claim. As an example, on its Facebook page for its Nashville office, Defendant HRC Medical has the following comment:

Great Review! Rachel – Nov. 22, 2011 HRC Medical Center has changed my life! My skin is so clear, *and the hair I was loosing [sic] is thicker and smoother now than it has ever been!* My confidence level has grown and I am not ashamed to meet people now! Thank you for all you have done! (emphasis added)

372. Defendant Don Hale made the following statement in a press release for Defendant HRC Medical about its BHRT, in relevant part:

Actress Suzanne Somers, preaching about the wonders of bioidentical hormones for more than a decade recently said menopause hit on her 50th birthday and almost ruined her life. 'It began a three-year odyssey of not sleeping, moodiness, weight gain, *changes in my hair*, changes in my skin, body itches [and] rashes. By replacing my hormones with bioidentical hormones, I got my life back, my health, my figure-I got my happiness back,' she says. '*Everything in my life is better.*' *We want to tell this story to the masses and we certainly have stores of many happy and healthy clients to share, reflects Don Hale of HRC Medical Center.* (emphasis added)

373. Defendant Dan Hale, on behalf of Defendant HRC Medical, in advertisements for Defendant HRC Medical's BHRT, made the following statement, in relevant part:

By age 35 the hormone progesterone will begin to drop off in women. This causes changes in the menstrual cycle, agitation, poor sleep, and *hair loss*. . . . *The good news is you do not have to just live with it.* You can have the same natural hormones you had when you were 25. You can regain that youthful feeling. *You can prevent many of the negative consequences of the loss of hormones.* Let HRC Medical help you. Dr. Dan Hale 10/10/11. (emphasis added)

374. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure hair loss or can thicken a user's hair.

375. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure hair loss or can thicken a user's hair.

376. Numerous female consumers of Defendant HRC Medical's BHRT in Tennessee have experienced hair loss on their head after taking Defendant HRC Medical's BHRT.

377. One female consumer who took Defendant HRC Medical's BHRT stated the following:

After four months of taking the treatment, the hair on my head began to fall out. Prior to this happening, I had never experienced excessive hair loss on my head. . . To this day, . . . the hair on my head has continued to fall out. . . . The hair loss from my head became so bad that I would find clumps of hair in my pool. On one occasion, after a week's time, there was a clump of my hair the size of a dinner plate circulating in the center of my pool where the water from the filters is directed."

378. Another female consumer stated the following about her experience taking Defendant HRC Medical's BHRT:

After four months of taking the treatment, the hair on my head began to fall out. Prior to this happening, I had never experienced excessive hair loss on my head . . . To this day, . . . the hair on my head has continued to fall out. . . . Since stopping treatments with HRC, I have spent at least \$600 on Nioxin and other products to try and correct hair loss. I still currently experience hair loss on my head. Prior to starting hormone replacement therapy at HRC, I had long, thick, wavy hair of which I was extremely fond and that I considered to be my pride and joy. [I] asked my husband to stop running his fingers through my hair because I was concerned that more hair would fall out in clumps.

379. Male consumers of Defendant HRC Medical's BHRT in Tennessee have also experienced hair loss on their head after taking Defendant HRC Medical's BHRT.

EXPRESS WEIGHT LOSS AND WEIGHT CONTROL CLAIMS

380. Defendant HRC Management Midwest, Defendant HRC Medical, Defendant Don Hale, on behalf of Defendant HRC Medical, and Defendant Dan Hale, on behalf of Defendant HRC

Medical, have all claimed that Defendant HRC Medical's BHRT can cause weight loss when those claims were false, deceptive, and/or not adequately substantiated.

381. Defendant HRC Medical has stated the following in a brochure distributed in Tennessee for its BHRT, in relevant part:

Hormone deficiency symptoms we don't have to live with: . . . weight gain . . .
(emphasis added)

382. Defendant HRC Medical and Defendant Dan Hale, on behalf of Defendant HRC Medical, have used "weight loss" claims, like "lose weight," in backgrounds, posters, and other advertising materials for Defendant HRC Medical's BHRT. An example is shown below in Figure 18:

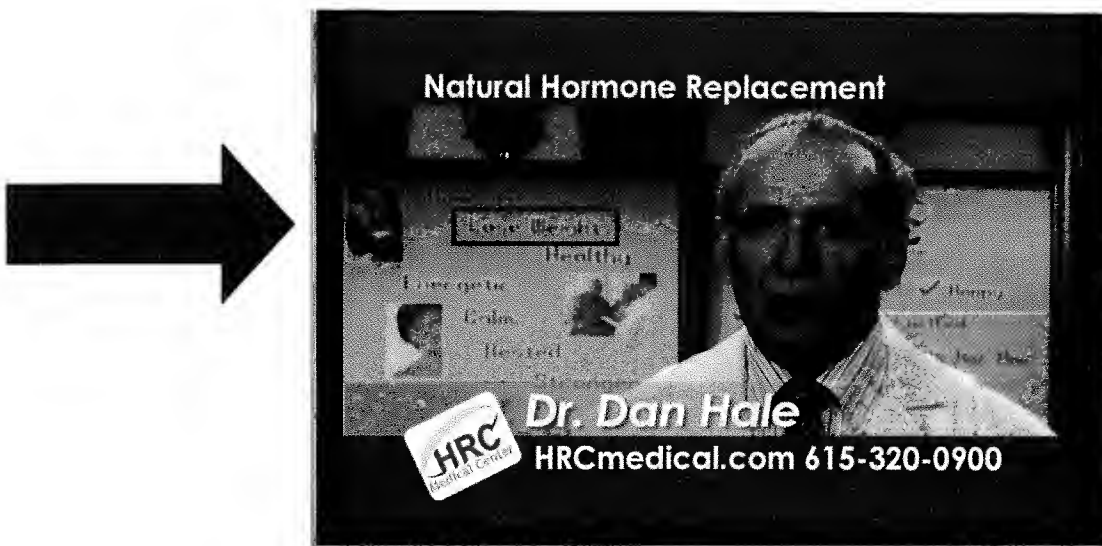


Fig. 18
(Red rectangle added)

383. In a Frequently Asked Questions document about Defendant HRC Medical's BHRT, Defendant HRC Medical states the following:



FREQUENTLY ASKED QUESTIONS...

- **When will I start losing weight?**
 - The answer to this question is different for everyone. Hormone patients who incorporate a healthy lifestyle (diet and exercise), lose weight at a faster rate than those who don't.
 - Take advantage of the high levels of testosterone circulating through your body.
 - Weight bearing exercises will help you build strong, toned, lean muscle mass.
 - Building lean muscle will burn fat, speed up your metabolism, and make you feel great!

384. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

Testosterone in women gives the ability to maintain a healthy weight . . . (emphasis added)

385. In an advertisement for BHRT on WSMV, Defendant Dan Hale, on behalf of Defendant HRC Medical stated the following, in relevant part:

The main two [hormones] that we deal with is the *testosterone* and that gives you certain things, the energy, the sex drive, *it helps you lose the weight.* (emphasis added)

386. In an advertisement for BHRT on WSMV, Defendant Dan Hale, on behalf of Defendant HRC Medical stated the following, in relevant part:

We start losing our hormones and when we start losing the hormones, that when all the bad things begin happening. *So it's really not our fault that we can't lose weight.* It's not our fault that we feel tired. *It's because we don't have the hormones we had when we were 20 years old.* (emphasis added)

387. In a brochure distributed to prospective consumers in Tennessee about its BHRT, excerpted below in Figure 19, Defendant HRC Medical and Defendant HRC Management Midwest have asserted the following, in relevant part:

Our patients have self-reported life-changing IMPROVEMENTS in symptom relief. . Symptoms: Weight Control [Graph shows 63% in "significant" zone] (emphasis added)

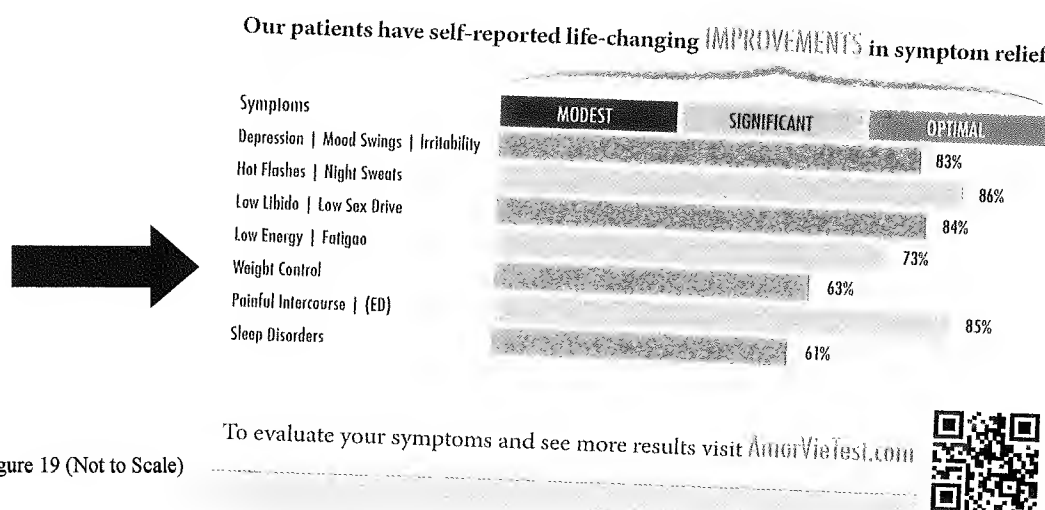


Figure 19 (Not to Scale)

388. On July 25, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook account for the Memphis office:

Hormone deficiencies and imbalances can have a severe negative impact on daily lifestyles in both men and women. Inadequate hormone levels can attribute to loss of energy, low sex drive, sexual dysfunction, *weight gain*, hot flashes and night sweats, loss of lean muscle, even depression and mood swings, to mention only a few. In many cases these negative effects are ignored or discounted by the [sic] traditional medicine. Some look at these symptoms as being part of the aging process and suffering individuals are told to “deal with it”, “it will pass” or “this comes with getting older”. *The good news that in most cases these conditions can be treated through use of our exclusive bio-natural Amor Vie® Therapy.* At HRC we achieve optimized hormone levels for our patients by restoring those levels back to that of their prime not just the levels for mid-life or senior adults. We are so confident that we can optimize an individual’s hormone levels we offer a written guarantee. *We do not only relieve our patients [sic] symptoms, we treat the actual cause of them.* (emphasis added)

389. Defendant Dan Hale, on behalf of Defendant HRC Medical, stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

Obesity Testosterone lowers insulin levels which allows weight loss. 100% of our patients who are overweight are low in hormones, especially testosterone. (emphasis added)

390. On July 19, 2011, Defendant HRC Medical stated the following about its BHRT on its Facebook page for its Knoxville office, in relevant part:

Did you know that hormones control every system of the body. Hormone replacement is a treatment of prevention of disease instead of cure. Most diseases . . . *obesity* . . . occur after age 40. 98% of the patients over 40 have low hormones. Let HRC Knoxville help balance your life. Contact our office @ (865) 670-0039 with any questions or to schedule your free consultation today. (emphasis added)

391. On February 16, 2012, Defendant HRC Medical has stated the following on its Facebook page for its Knoxville office, in relevant part:

Hormone deficiencies and imbalances can have a severe negative impact on daily lifestyles in both men and women. *Inadequate hormone levels can attribute* to loss of energy, low sex drive, sexual dysfunction, *weight gain*, hot flashes and night sweats, loss of lean muscle, even depression and mood swings, to mention only a few. In many cases these negative effects are ignored or discounted by traditional medicine. Some look at these symptoms as being part of the aging process and suffering individuals are told "to deal with it", "it will pass" or "this comes with getting older". *The good news is that in most cases these conditions can be treated through use of our exclusive bio-natural Amor Vie(R) Therapy.* At HRC we achieve optimized hormone levels for our patients by restoring those levels back to that of their prime not just the levels for mid-life or senior adults. *We are so confident that we can optimize an individual's hormone levels we offer a written guarantee. We do not only relieve our patients [sic] symptoms, we treat the actual cause of them.* (emphasis added)

392. Defendant HRC Medical has stated the following in an advertisement for its BHRT, in relevant part:

At age 30 both men and women start producing less testosterone. Men will decrease by 90% their production of testosterone from age 25 to 70. Most of us do not want to be producing 90% less of anything we had when we were 25. *Men will usually develop a belly even though they haven't changed their diet. . . .* The production of

testosterone is the first hormone to begin decreasing. *Men and women see this as weight gain and loss of muscle mass. Most will lose 10 ounces of muscle per year after age 30. This is about the size of a good steak. Lost every year. And replaced with fat. . . . [At the conclusion] These hormones can be replaced by natural hormones that are exactly like the hormones you had when you were 25. You can live a longer and healthier life. We all want our health to last as long as our life. Please let us help at HRC Medical. Dr. Dan. (emphasis added)*

393. Defendant Dan Hale, on behalf of Defendant HRC Medical, engaged in the following dialogue with WSMV in advertisements for BHRT:

DAN HALE: Amor Vie is a process replacing hormones with checking the blood to find out where your hormone deficiencies are. . . .

WSMV: So what are some common symptoms your patients are faced with when they come in and see you?

DAN HALE: There's a whole list of probably 50 different symptoms. . . . With men, it's putting on weight in or around the belly. . . .

WSMV: We've got a whole list of symptoms on the screen right there that people face [screen shows "weight gain" among other symptoms]. . . .

DAN HALE: The next thing is weight gain, so many women, especially, trying to lose weight, they exercise not seeing any results. . . .

DAN HALE: A loss of hormones causes a lot of symptoms. . . . *Without hormones, bad things begin to happen. Without hormones we develop Alzheimer's, high blood pressure, high cholesterol. We have weight gains [sic], especially around the belly and around the butt. We have loss of muscle development. So all of those things are caused because of loss of hormones we replace those hormones with natural hormones. (emphasis added)*

394. Defendant HRC Medical has stated the following in advertisements for its BHRT, in relevant part:

Amor Vie™ therapy is an effective way to restore one's health and alleviate the symptoms related to hormonal imbalance and deficiencies. Symptoms that indicate a lack of imbalance of Estrogen, Testosterone, or Progesterone Symptoms Affecting Both Males & Females . . . Weight Gain. . . (emphasis added)

395. Defendant Dan Hale, on behalf of Defendant HRC Medical, engaged in the following dialogue with WSMV in advertisements for BHRT:

WSMV: Now, what are some common symptoms your patients are faced with so viewers know if they have a possible hormone imbalance?

DAN HALE: There are a lot of symptoms related to loss of hormones. *With women, they're . . . going to put on weight. . . .* (emphasis added)

396. Defendant Don Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements for Defendant HRC Medical's BHRT:

DON HALE: The first thing we're doing is we check your blood level to see where your hormone levels are. From that we know where we want you to be and most people that come in that they have the symptoms of . . . *overweight* . . . those people we know the hormone levels are low.

VOICE OVER: The Amor Vie pellet is implanted under the skin through a tiny slit in your hip. Some people within a matter of a couple of days, they're feeling a difference. Within a matter of two weeks, they're usually getting the full benefit . . .

DON HALE: *People talk about the middle age spread. I was one that has always had to fight weight and I lost 26 pounds right after I did this.* (emphasis added)

397. On March 23, 2011, in a Facebook post for the Nashville office, Defendant Don Hale, on behalf of Defendant HRC Medical, has stated the following about Defendant HRC Medical's BHRT, in relevant part:

My wife and I both started the treatment 3 ½ years ago. It has changes [sic] our lives. Not only the energy, *weight control*, better sleep, but the passion it put back in our relationship has been amazing . . . (emphasis added)

398. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

INTERVIEWER: Ok, now, um, *the symptoms that women have and the symptoms that men have that can relieve these, that is affected by hormonal imbalance*, share those with us, please, if you don't mind.

DAN HALE: The most common thing that women complain of is poor sleep, restless leg syndrome, decreased sex drive, *weight gain*, tired all the time. Those things are in women. Men complain of tiredness all the time, the complaint of erectile dysfunction, *pot belly or weight gain*. *A lot of those things are caused from lack of hormones.* (emphasis added)

399. Defendant HRC Medical stated the following in a press release in which both Defendant Don Hale and Defendant Dan Hale are quoted, in relevant part:

Actress Suzanne Somers, preaching about the wonders of bioidentical hormones for more than a decade recently said menopause hit on her 50th birthday and almost ruined her life. 'It began a three-year odyssey of not sleeping, moodiness, weight gain, changes in my hair, changes in my skin, body itches [and] rashes. By replacing my hormones with bioidentical hormones, I got my life back, my health, my figure-I got my happiness back,' she says. 'Everything in my life is better.' 'We want to tell this story to the masses and we certainly have stories of many happy and health clients to share,' reflects Don Hale of HRC Medical Center. 'To find something that can make anyone feel like they are in the prime of their life, it would simply be wrong to keep it a secret!' ### Founded in 2005, by Dr. Dan Hale and Don Hale, HRC Medical Center provides the latest in anti-aging techniques. . . . (emphasis added)

400. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT on WSMV, in relevant part:

DAN HALE: The main two [hormones] we deal with is the testosterone and that gives you certain things, the energy, the sex drive, *helps you to lose the weight . . .* the estrogen is the hot flashes, the night sweats, the vaginal dryness that can cause painful intercourse. . . . (emphasis added)

401. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

Loss of testosterone is seen as weight gain You can prevent many of the negative consequences of the loss of hormones. Let HRC Medical help you. Dr. Dan Hale. (emphasis added)

402. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT, in relevant part:

INTERVIEWER: Now, what are, what symptoms are they faced with when they come in to see you?

DAN HALE: Women are going to have hot flashes, night sweats, vaginal dryness. They're going to be tired all of the time. *Having weight gain*, don't know why . . .

INTERVIEWER: No, I'm curious though. What age do most people consider this?

DAN HALE: Well, it honestly can be almost any age. Up from 22 to 92. We have these women, young girls in their 20s putting on weight and they don't know why. That's the problem with them is their testosterone may be too low. They need to have more energy where they- testosterone will help, take, will help build muscle mass instead of forming fat. (emphasis added)

403. On WZTV, Nashville's local Fox affiliate, Defendant HRC Medical paid for an advertisement for its BHRT using WZTV's on-air personalities which stated the following, in relevant part:

Low or unbalanced levels of these important hormones can cause . . . *weight gain* . . . HRC Medical uses bioidentical hormone replacement therapy to treat these and other symptoms. If you want to get back to feeling like yourself, the people at HRC Medical can help. Hormone replacements can rejuvenate your system giving you more energy, better focus. In essence, turn back the clock in so many ways. Our treatments are all natural safe, quick and long lasting. Thousands in Middle Tennessee have already discovered the difference made by hormone replacement. Now, it's your turn. Call for your free consultation today. HRC Medical – 320-0900. (emphasis added)

404. Defendant HRC Medical has stated the following, in relevant part, in advertisements for its BHRT:

Our patients have self-reported life-changing IMPROVEMENTS in symptom relief. Depression/Mood Swings/ Irritability, Hot Flashes/Night Sweats, Low Libido/Low Sex Drive, Low Energy/Fatigue, *Weight Control*, Painful Intercourse/ED, Sleep Disorders . . . (emphasis added)

405. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following in advertisements for Defendant HRC Medical's BHRT:

DAN HALE: *You can lose weight. We've heard of the middle-aged spread. Well, that happens not because we're middle aged, it is because we don't have the*

hormones we use to have. A lot of times men say, "I still have a chest, it's just dropped." Well, it doesn't have to drop. And the reason why those things happen is because of lack of hormones. Migraine headaches a lot of times of helped by bioidentical hormone replacement therapy.

FEMALE INTERVIEWER: *It's really exciting to know that there is something that can be done for those things and that it's safe.*

DAN HALE: *Sure, I love doing this.* (emphasis added)

406. On June 1, 2012, and July 20, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following purported consumer testimonial on their Facebook page for the Memphis office:

I cannot express how much my life has improved with the natural hormone treatment. I have been looking for relief since my last daughter was born, 29 years ago. Every doctor that I went to said that it was normal and my hormones were fine. I knew that I should feel better, that anxiety and depression were not normal. All that was offered was medication for mood. But, medication only covered up the problem, any medication used to alter mood swings only covered up the problems, you may not feel sad, but you do not feel happy. It also reduces your sex drive, one contribution to my divorce after 26 years. Once I started with HRC I found relief. I am into my second year and would never give up the treatment. My overall disposition has improved, I feel happy and energetic, *my weight is now under control and I feel alive again.* I am a licensed massage therapist and I have recommended HRC to several of my clients. Several have started treatment and they are very happy with the results. For one client it has helped with her headaches. Each of us have experienced a different improvement, some with the first insert, while others it took time for the hormones to work. At every opportunity I share my experience with natural hormone replacement, knowing that there are many women and men that would benefit from this treatment. My second daughter is looking into starting this treatment. HRC Patient. (emphasis added)

407. On June 28, 2012, and July 21, 2012, Defendant HRC Medical and Defendant HRC Management Midwest stated the following, in relevant part, on their Facebook page for the Memphis office:

Many of our patients are driven to hormone replacement therapy because they somehow believe the weight will magically melt off when they begin treatment. *The Amor Vie Therapy can have a dramatic improvement in the reduction of weight.* But

it comes with the holistic impact of the improvement in many areas that lead the individual to focusing on attacking that area of their life. Contact HRC Medical Center to learn more! (emphasis added)

408. On August 8, 2012, Defendant HRC Medical and Defendant HRC Management Midwest stated the following on their Facebook page for the Memphis office:

Common symptoms such as restless sleep, anxiety, depression, mood swings, *weight gain*, dry skin, migraine headaches, lack of energy, or low sex drive are indicators that hormone levels are not in proper balance at the proper levels. Many young men and women have low hormone levels just because they do not take proper care of their bodies.

409. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT can cause a consumer to lose weight or have improved weight control.

410. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT can cause a consumer to lose weight or have improved weight control.

411. Many consumers of Defendant HRC Medical's BHRT have, in fact, gained weight while taking BHRT.

EXPRESS CLAIMS ABOUT REPLACING HORMONES TO PRIME OF LIFE LEVELS

412. All Defendants have falsely, deceptively, and/or without adequate substantiation claimed that Defendant HRC Medical's BHRT restores a consumer's hormones to the levels that the consumer had when she or he was in her or his twenties and thirties or to the levels she or he had in her or his prime.

413. The key component of Defendant HRC Medical's BHRT for both men and women is testosterone.

414. For women in their twenties and thirties, testosterone is between 10 to 70 ng/dL in 95% of normal, healthy women though some laboratory ranges place this number between 0 and 65 ng/dL.

415. For women, Defendant HRC Medical's BHRT is intended to take a woman's testosterone levels to levels that do not naturally exist in most women—including women in their twenties and thirties.


416. Similarly, for men in their twenties and thirties, testosterone is between 200 and 700 ng/dL in 95% of men.

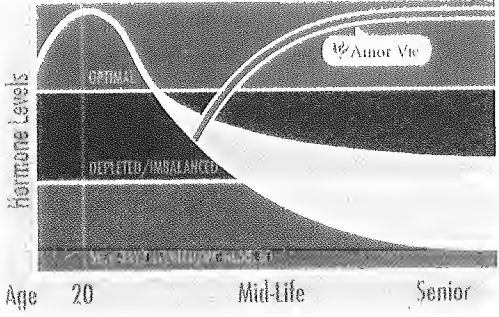
417. For men, Defendant HRC Medical's BHRT is intended to take a man's testosterone levels to levels that do not naturally exist in most men—including men in their twenties and thirties.

418. Defendant HRC Medical and Defendant HRC Management Midwest have stated the following, as quoted and excerpted below in Figure 20, in a brochure distributed in Tennessee to prospective consumers of its BHRT.

Renew! **Naturally** derived Amor Vie™ will renew the hormone levels of your prime! Unlike many other hormone treatments, your Amor Vie™ therapy is personally designed to restore the optimal hormone levels found in your early 20's, not just the levels for a mid-life or senior adult.

RENEW!

Naturally derived  Amor Vie will renew the hormone levels of your prime!




Unlike many other hormone treatments, your  Amor Vie therapy is personally designed to restore the optimal hormone levels found in your early 20's, not just the levels for a mid-life or senior adult.

Figure 20 (excerpt) (Not to scale)

419. Defendant HRC Medical has stated the following, in relevant part, about its BHRT:

This is seen as a loss of the love-life we had when we were younger. *All of these losses can be re-gained [sic] by returning your testosterone to values we used to have.* (emphasis added)

420. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, about Defendant HRC Medical's BHRT:

That is why it is crucial to replace these lost hormones. *But the key is to replace them (estradiol, progesterone, and testosterone) with hormones that are an exact duplicate of those we had when we were 25 years old . . . Natural hormones as we had when we were 25 do not have the side effects associated with synthetics.* (emphasis added)

421. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in advertisements for Defendant HRC Medical's BHRT:

DAN HALE: *Bioidentical means biologically identical to the hormones you had when you were 20 years old.*

NARRATOR: *Wouldn't we all want to feel twenty again?* (emphasis added)

422. On February 16, 2012, Defendant HRC Medical has stated on its Facebook page for its Knoxville office, the following, in relevant part, about its BHRT:

At HRC we achieve optimized hormone levels for our patients by restoring those levels back to that of their prime not just the levels for mid-life or senior adults. We are so confident that we can optimize an individual's hormone levels we offer a written guarantee . . . (emphasis added)

423. Defendant HRC Medical has stated the following, in relevant part, in advertisements for its BHRT:

Our pellets are identical to the hormones created naturally by the body when we were in our prime. (emphasis added)

424. On July 25, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following, in relevant part, on their Facebook account for the Memphis office:

Hormone deficiencies and imbalances can have a severe negative impact on daily lifestyles in both men and women. Inadequate hormone levels can attribute to loss of energy, low sex drive, sexual dysfunction, weight gain, hot flashes and night sweats, loss of lean muscle, even depression and mood swings, to mention only a few. In many cases these negative effects are ignored or discounted by the [sic] traditional medicine. Some look at these symptoms as being part of the aging process and suffering individuals are told to "deal with it", "it will pass" or "this comes with getting older". The good news that in most cases these conditions can be treated through use of our exclusive bio-natural Amor Vie® Therapy. *At HRC we achieve optimized hormone levels for our patients by restoring those levels back to that of their prime not just the levels for mid-life or senior adults.* We are so confident that we can optimize an individual's hormone levels we offer a written guarantee. We do not only relieve our patients [sic] symptoms, we treat the actual cause of them. (emphasis added)

425. Similarly, on June 29, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following, in relevant part, on their Facebook account for the Memphis office:

@HRC Medical patient sampling indicates that regular treatment provides a sustained #hormone level, *consistent with that of our prime.* (emphasis added)

426. Defendant HRC Medical has stated the following, in relevant part, in advertisements for its BHRT:

The reduction of the Hormones Estrogen, Progesterone and Testosterone in men can cause a myriad of symptoms affecting our health and the way we feel. HRC's AMOR VIE® therapy program is designed to help men & women to . . . RESTORE your Hormones, RENEW your life, and REJOICE in your success. . . . *When hormone levels are normal as they were in one's twenties, usually sleep under normal conditions is not a problem.* (emphasis added)

427. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, about Defendant HRC Medical's BHRT:

But the good news is that we do not have to tolerate the ravages of loss of hormones. *These hormones can be replaced by natural hormones that are exactly like the hormones you had when you were 25.* You can live a longer and healthier life. . . . Please let us help at HRC Medical. Dr. Dan. (emphasis added)

428. Defendant HRC Medical has stated in a brochure distributed in Tennessee to prospective customers for its BHRT, the following, in relevant part:

Our treatment plan may provide you with the solution that, thus far, has been elusive to alleviating persistent symptoms caused by low testosterone. You may find more youthful energy return to benefit you and those around you by *restoring* your testosterone with bio-available natural testosterone through AMOR VIE® Therapy at HRC Medical. Individual results may vary. Please call us to see if AMOR VIE® is right for you. *RESTORE, RENEW, & REJOICE.* (emphasis added)

429. On January 5, 2012, Defendant HRC Medical stated the following, in relevant part, on its Facebook page for its Nashville office:

Naturally derived Amor Vie will renew the hormone levels of your prime.
(emphasis added)

430. Elsewhere, Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part:

Without hormones, we're just an empty shell of ourselves. I didn't get that quote from me – that was from Suzanne Somers – one of her books. But it's so – she hit the nail on the head because without hormones, we wish we were like we were but we're just not. We're not the same people. *But when we can replace those hormones, we're back like we were when we were 20–25 years old* and every day of my work day I have people say thank you for what you've done for me because I have my life back.

431. Defendant Don Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements about Defendant HRC Medical's BHRT:

No one can find any evidence that *having your hormone levels raised back like they were in your youth* can hurt you in any way if it's done with natural hormones as opposed to synthetic hormones. (emphasis added)

432. Defendant HRC Medical has stated in advertisements for its BHRT, the following, in relevant part:

We must first replace and restore [hormones that have] been lost over the years. (emphasis added)

433. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements for Defendant HRC Medical's BHRT on WSMV:

But when we can replace those hormones, we're back like we were when we were 20-25 years old . . . (emphasis added)

434. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements for Defendant HRC Medical's BHRT:

So all of those deficiencies happen not because you get older, *but because we don't have the hormones we used to have when we were younger.* (emphasis added)

435. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements for Defendant HRC Medical's BHRT:

We use hormones that are natural, hormones that are *like the hormones you had when you were 25 years old* that are identical to those kinds of hormones, they're not the synthetic kind. (emphasis added)

436. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's BHRT replaces a consumer's hormone levels to the levels that he or she had in his or her twenties or thirties or during his or her prime.

437. Clinical studies, research, and/or trials do not show that Defendant HRC Medical's BHRT replaces a consumer's hormone levels to the levels that he or she had in his or her twenties or thirties or during his or her prime.

EXPRESS FABRICATED AND CONTRADICTORY SUBSTANTIATION CLAIMS

438. In materials handed out to consumers in Tennessee to promote Defendant HRC Medical's BHRT, Defendant HRC Medical has used fabricated quotes about the purported benefits, efficacy, risks, and side effects of each hormone component of its therapy.

439. As an example, in a document titled "Consultant References," purporting to list references for "Estrogen," with the document number 100.007 noted in the lower right corner, Defendant HRC Medical uses the following quote:

"Estradiol and progesterone demonstrated no increased risk of breast cancer. Synthetic estrogen (Premarin®) and synthetic progestins (medroxyprogesterone and noresterone) all dramatically increased the risk of breast cancer. This was a ten year study of over 100,000 women, the largest and longest study to date comparing natural hormones to synthetic hormones". *Breast Cancer Res Treat* 2007; 101: 125-134.

440. Not only is the quote not found in the study cited, the study did not concern 100,000 women, *but instead tested the effects of two combination therapies administered through marshmallows and Crystal Light on twenty-five postmenopausal, ovariectomized monkeys (cynomolgus macaques).*

441. In the same document, with the reference number 100.007 in the lower right corner, Defendant HRC Medical stated the following:

“Estrogen reduces the incidence of Alzheimer’s disease by 50%. JAMA 2002; 288:2123-2129.”

442. Not only is the quote not found in the study but it is a distortion of the limited findings of an observational study. In fact, the observational study cited concerned CEE, which all Defendants claim to be completely different than Defendant HRC Medical’s BHRT.

443. Defendants cannot, as they have all done, simultaneously claim that Defendant HRC Medical’s BHRT is completely different and divorced from the risks and side effects of “synthetic” CEE and then attempt to substantiate benefit claims based on the same CEE that they claim are completely different.

444. Similarly, in a document titled “Consultant References” purporting to list references regarding “Progesterone,” with the document number 100.008 noted in the lower right corner, Defendant HRC Medical states the following:

“Due to the side effects of synthetic progestin’s, natural progesterone is preferred. Progesterone has proven bio-availability and no side effects making it the preferred hormone for menopause.” American Family Physicians 2000; 62: 1339-46.

445. Not only does the quoted material not appear anywhere in the cited article, the article expressly mentions side effects associated with micronized progesterone, and the quoted material vastly overstates the limited findings of the article.

446. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that the cited studies contain the quoted material, that the quotes are an accurate reflection of the cited studies, and that the hormones studied were non-synthetic.

EXPRESS CLAIMS ABOUT NUMBER OF CREDIBLE STUDIES

447. Defendant HRC Medical and Defendant Dan Hale, on behalf of Defendant HRC Medical, have made repeated misrepresentations about the number of credible studies or a purported large body of credible studies that support certain claims.

448. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated in an advertisement for Defendant HRC Medical's BHRT on WSMV, the following, in relevant part:

INTERVIEWER: Can you talk about that? Is it safe?

DAN HALE: I'm glad you asked that question. So many people that they think that aw, it could cause heart attacks, strokes, blood clots, but every time they do those kind of studies they're talking about the synthetic kind. *Every study done, there's many, many hundreds of studies that is [sic] out there that show hormones actually protect it, if it's the kind we had when we were 25 years old.* (emphasis added)

449. Elsewhere, in an article written by Defendant Dan Hale distributed to consumers in Tennessee and posted on Defendant HRC Medical's Facebook page for its Knoxville office, Defendant Dan Hale, on behalf of Defendant HRC Medical, stated the following, in relevant part:

Many studies have been done showing the beneficial effects of replacing these hormones as they decline. As a matter of fact, these studies show that the earlier the better, even replacing diminishing hormones in perimenopause (the early stages of menopause) is more beneficial than waiting until menopause. Many studies can be found on medical web sites showing there is less osteoporosis, coronary artery disease, depression, an increase in sex drive, elimination of hot flashes, vaginal dryness and night sweats, an increase in muscle mass in men and women, less need for erection dysfunction medication in men, greatly improved sleep, more energy, much improve [sic] self-esteem, and a resolution of restless leg syndrome. (emphasis added)

450. Defendant Dan Hale, on behalf of Defendant HRC Medical, has repeated this false assertion in other formats. In advertisements for Defendant HRC Medical's BHRT, Defendant Dan Hale stated the following:

Bio-identical hormones therapy are [sic] safe. They're not the kind of hormones that are unsafe. The other kind of hormones for hot flashes called conjugated estrogen

and they are not safe. *We know that because on the Women's Health Initiative trial, they caused a lot of problems with breast cancer, cervical cancer, heart disease, blood clots. The bio-identical hormones never, ever do that. As a matter of fact, a lot of studies show that probably they're somewhat protective in some of those things.* Thank you very much. (emphasis added).

451. In advertisements, Defendant HRC Medical has used consumer testimonials that make the same misrepresentation. As an example, in a video advertisement posted on its Facebook page for Defendant HRC Medical's Nashville office, a consumer states the following:

My mom went through menopause and she was on the synthetic hormones and I remember seeing the news and she had to get off of them and it was very scary because I picked up the phone to say, do you realize what this could be doing to you *and so when I started investigating and doing the research like they tell you to do for all natural hormone replacement therapy, I was impressed. I was amazed that you know there have been lots of studies and I felt really confident that what I was doing was going to be safe and it was going to be effective and so that's what made me want to go for it.* (emphasis added)

452. On a prior version of Defendant HRC Medical's website, www.hrcmedical.com, Defendant HRC Medical has stated the following about its BHRT:

The Benefit Beyond Feeling Better

Most everyone will receive relief of their symptoms: tiredness, depression, poor sleep, erectile dysfunction, vaginal dryness, hot flashes, and loss of muscle tone. But there are many other benefits beyond just feeling better. Osteoporosis shows reversal of bone loss with additional new bone laid down. Many times blood pressure is lowered as well as cholesterol. *Many studies show positive results of less strokes, ovarian and heart disease.* (emphasis added)

453. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that benefit, efficacy, safety, or side effects claims for Defendant HRC Medical's BHRT are supported by more credible scientific support than they actually are.

EXPRESS COMPOUNDING PHARMACY CLAIMS

454. Defendant HRC Medical has falsely told consumers that its compounding pharmacy was FDA-approved, and Defendant HRC Medical and Defendant HRC Management Midwest have deceptively told consumers that the compounding pharmacy adheres to high quality control standards and produces optimized, time-released hormone pellets.

455. None of the compounding pharmacies that Defendant HRC Medical has used to supply its hormone pellets is or ever has been FDA-approved.

456. Further, all Defendants have knowledge of quality control problems at the MasterPharm compounding pharmacy, including problems with the inconsistent compression of pellets, which makes dosing nearly impossible and potentially dangerous.

457. Defendant HRC Medical has stated the following in promotional materials for its BHRT, which were handed out to consumers:

Our pellets are bio-engineered using all natural ingredients by our FDA approved compounding pharmacy. Our pharmacy is one of only two FDA approved pharmacies of their kind in the United States. (emphasis added)

458. Elsewhere, apart from claims about FDA approval, Defendant HRC Medical has claimed that MasterPharm, the compounding pharmacy that it uses to supply its pellets, has high quality control standards, when all Defendants have known of continuing quality control problems this compounding pharmacy has had with pellets implanted in consumers, especially with the consistency of the compression of the pellets.

459. Defendant HRC Medical has stated the following in promotional materials for its BHRT, which were handed out to consumers:

Our pellets are bio-engineered using all natural ingredients by MasterPharm, our compounding pharmacy. MasterPharm's facilities operate in strict compliance with ASHP, USP/NF 795 and 797, JCAHO and Iso 9001 quality control standards.

460. Likewise, on June 26, 2012, Defendant HRC Medical and Defendant HRC Management Midwest posted the following on their Facebook account for the Memphis office:

HRC Medical Centers uses *time released pellets that optimize our patients#* [sic] *hormone levels* and maintain them for extended periods of time. (emphasis added)

461. In fact, as known to Defendant HRC Medical, Defendant Don Hale, and Defendant Dan Hale, the compression problems with MasterPharm's pellets make the time that the pellets are released wholly unpredictable. If the pellet is compressed too loosely, the hormones are released too soon. If the pellet is compressed too tightly, the hormones have difficulty being released into the blood, which can result in super spikes of hormones if another pellet is added to reach Defendant HRC Medical's target blood hormone levels.

462. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical's compounding pharmacy has been FDA-approved, adheres to high quality control standards, and produces optimized, time-released hormone pellets.

EXPRESS AND IMPLIED CLAIMS ASSERTING HORMONE EXPERTISE

463. Until recently, Defendant Dan Hale has acted as the chief spokesperson for Defendant HRC Medical and has appeared in countless advertisements for Defendant HRC Medical's BHRT.

464. In a variety of ways, all Defendants have misrepresented the extent of the expertise and experience of Defendant HRC Medical's and Defendant HRC Management Midwest's medical staff with the hormone replacement therapy, which are intended to give consumers a greater comfort level in purchasing Defendant HRC Medical's BHRT.

465. Initially, in advertisements for Defendant HRC Medical's BHRT, Defendant Dan Hale has falsely stated the number of years he has practiced medicine.

466. Defendant Dan Hale, on behalf of Defendant HRC Medical, has stated the following, in relevant part, in advertisements for Defendant HRC Medical's BHRT:

I've been practicing medicine for 35 years and so, I've practiced the other way and I feel so much better now because I can prevent these things. I can treat the actual problem instead of just giving medicine that really has so many side effects. (emphasis added)

467. Defendant Dan Hale's statement is false because it includes a five and a half year period in which Defendant Dan Hale did not, and could not, lawfully practice medicine.

468. Defendant Dan Hale received his doctorate of osteopathy in 1974 at the Kirksville College of Osteopathy in Kirksville, Missouri.

469. On November 8, 1995, Defendant Dan Hale entered into an Agreed Order with the Osteopathy Board with the Tennessee Department of Health, whereby he surrendered his osteopathic medical license.

470. His osteopathic medical license was reinstated by the Osteopathy Board with the Tennessee Department Health on May 25, 2001.

471. All Defendants have misrepresented the extent of Defendant Dan Hale's expertise with hormone replacement therapy in advertisements for Defendant HRC Medical's BHRT.

472. Defendant Dan Hale does not have an extensive educational history with respect to hormone replacement therapy or any expertise about the subject matter. Defendant Dan Hale was first exposed to hormone replacement therapy when he went with Trina Lonning, the unlicensed medical assistant that Defendants hired to set up Defendant HRC Medical's hormone replacement program, to another BHRT provider for a single two-day training conference.

473. Defendant Dan Hale is a doctor of osteopathy who has spent the overwhelming portion of his professional life in fields unrelated to hormone replacement. Defendant Dan Hale has been a family practitioner, an emergency room doctor, a pain clinic doctor, not practicing medicine at all, a doctor performing non-FDA approved cosmetic therapies, or a hair transplant doctor.

474. Defendant Dan Hale has no specialty board certification recognized by the Tennessee Department of Health. His limited training with hormone replacement comes from a certification he received in 2007 from Cenegenics, a multi-level marketing company which teaches and sells “age management” techniques, and from brief time spent with Dr. Gino Tuteria, an Arizona-based doctor, who also sells BHRT in pellet form.

475. Defendant HRC Medical’s advertisements for its BHRT that feature Defendant Dan Hale often refer to Defendant Dan Hale as a hormone replacement expert.

476. In a brochure distributed to prospective consumers in Tennessee for Defendant HRC Medical’s BHRT, excerpted below as Figure 21, Defendant HRC Medical has stated the following, in relevant part, about Defendant Dan Hale’s hormone replacement experience:

Dr. Dan Hale is HRC’s
medical director.
Dr. Hale is one of the leaders
in Natural Bio-Equivalent
Hormone Replacement
by lecturing extensively
teaching other physicians
this specialized discipline.



Figure 21 (Not to Scale)

477. The basis for the claim “by lecturing [sic] extensively teaching other physicians this specialized discipline,” is not that Defendant Dan Hale lectures or teaches about hormones to third-party medical professionals. Rather, this statement refers to Defendant Dan Hale training doctors employed by a given HRC Medical franchise who are required or strongly incentivized to attend, based on his own very limited training.

478. Elsewhere, Defendant HRC Medical has stated the following in promotional materials for Defendant HRC Medical’s BHRT:

Feel the way you did when you were young. Come to HRC Medical Nashville and get your life back. Our board certified doctors are here to assist you. Our doctors, after many years of General Medical Practice are now on the cutting edge of Hormone Replacement Therapy

479. The doctors who have been employed at Defendant HRC Medical’s Nashville and Knoxville offices have never possessed a specialty board certification in obstetrics and gynecology, endocrinology, or any other practice area related to hormone replacement therapy.

480. Elsewhere, on Defendant HRC Medical’s website, Defendant Don Hale has stated the following:

We design your treatment to respond to your unique needs & constantly monitor your progress with close direction and oversight by our *highly trained* and focused *medical staff*. Hormones are our specialty. (emphasis added)

481. Likewise, on July 17, 2012, Defendant HRC Medical and Defendant HRC Management Midwest stated the following on their Facebook page for the Memphis office:

We design your treatment to respond to your unique needs & constantly monitor your progress with close direction and oversight by our *highly trained* and focused medical staff. Hormones are our specialty. (emphasis added)

482. As well known to Defendant Don Hale, who has hiring and firing authority at Defendant HRC Medical, Defendant HRC Medical's and Defendant HRC Management Midwest's medical staff have not been "highly trained"—either in terms of hours spent studying hormone replacement therapy, through passage of an exam concerning hormone replacement therapy or a related field, or by otherwise demonstrating proficiency with respect to hormones or a related field. In fact, as known to Defendants Don Hale and Dan Hale, the entire hormone program at Defendant HRC Medical was set up and administered by an unlicensed medical assistant and its medical staff has had only a nominal amount of training, if any, relating to hormones. The limited training that the medical staff has received involved the flawed reference sheets containing fabricated quotes and contradictory studies themselves or similar materials.

483. As known to Defendant Don Hale, Defendant HRC Medical has struggled to maintain licensed professionals, much less ones who have training in hormone replacement. At one point, Defendant HRC Medical was so desperate to retain licensed staff that they kept a registered nurse, who performed BHRT pellet inserts and was thought by Defendant HRC Medical management and other employees to be under the influence of illicit drugs on occasion at work, on staff despite her admission that she had pulled the incorrect consumer files and implanted at least two consumers with hormones meant for another person. Defendant HRC Medical did not fire this registered nurse until she failed a drug test approximately two months later because Defendant HRC Medical wanted a registered nurse to be on staff.

484. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant Dan Hale, the chief medical spokesperson for Defendant HRC Medical's

BHRT, and that other employees or contractors of Defendant HRC Medical or Defendant HRC Management Midwest have expertise or experience in medicine in general or with hormone replacement specifically.

EXPRESS CLAIMS OF SATISFIED BHRT CONSUMERS

485. Defendant HRC Management Midwest, Defendant HRC Medical, and Defendant Don Hale, on behalf of Defendant HRC Medical, have all falsely claimed in advertisements that they have more satisfied consumers of their BHRT than they actually do.

486. For example, on its Facebook page for the Nashville office, Defendant HRC Medical has stated the following, in relevant part:

We are one of the leading experts in our field successfully treating *over 30,000 satisfied patients*. (emphasis added)

487. Defendant HRC Medical does not have 30,000 satisfied patients for its BHRT or anywhere close to this amount.

488. Elsewhere, Defendant Don Hale, on behalf of Defendant HRC Medical, has stated the following:

Our unparalleled experience with 35,000 patients, *and a 97% success rate*, as supported by our patients overwhelming feedback, gives us confidence that our proprietary AMOR VIE therapy is the right choice for most people who suffer the ravages of hormone depletion. (emphasis added)

489. Defendant HRC Medical's BHRT does not have a 97% success rate among all of those have undergone the therapy—a fact that Defendant Don Hale knows to be false.

490. Likewise, on June 1, 2012, and July 17, 2012, Defendant HRC Medical and Defendant HRC Management Midwest stated the following on their Facebook page for the Memphis office:

Our unparalleled experience with 35,000 patients, and a 97% success rate, as supported by our patients overwhelming feedback, gives us confidence that our proprietary AMOR VIE therapy is the right choice for most people who suffer the ravages of hormone depletion. We design your treatment to respond to your unique needs & constantly monitor your progress with close direction and oversight by our highly trained and focused medical staff. Hormones are our specialty. (emphasis added)

491. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that Defendant HRC Medical has more satisfied consumers of its BHRT than it actually does.

MATERIAL OMISSIONS IN ADVERTISING AND PROMOTIONAL MATERIALS

492. Neither Defendant HRC Medical, Defendant HRC Management Midwest, Defendant Dan Hale, nor Defendant Don Hale in the examples where they make statements about BHRT in advertisements and promotional materials, have ever clearly and conspicuously disclosed any of the serious side effects or potential risks of taking Defendant HRC Medical's BHRT in any of the marketing for Defendant HRC Medical's BHRT. In fact, as shown above, Defendants have expressly said the opposite, namely that Defendant HRC Medical's BHRT is completely safe, safe, or involves no or minimal side effects or risks.

493. Additionally, Defendant Don Hale by himself and through his son, Dane Hale, has specifically instructed sales consultants not to mention specific risks, side effects, or get "too technical" in their description of Defendant HRC Medical's BHRT. Dane Hale specifically told Andrea Bernard, a sales consultant, to refrain from telling consumers that they were not candidates for Defendant HRC Medical's hormone replacement therapy. Dane Hale also specifically told

Andrea Bernard not to mention risks associated with the therapy because otherwise “we’ll never have anybody come in here” or words to that effect.

494. Defendants have never disclosed, clearly and conspicuously or otherwise, that Defendant HRC Medical’s BHRT increases a consumer risk of developing serious medical conditions, such as endometrial cancer, tissue edema, and changes in lipids.

495. Further, Defendants have never clearly and conspicuously disclosed that Defendant HRC Medical’s BHRT includes the possible increased risk of breast cancer. This possible risk is increased in women who previously had breast cancer. In fact, Defendant HRC Medical and Defendant Dan Hale have stated the exact opposite, namely that their BHRT has actually been shown to protect against breast cancer.

496. Curiously, in more recent versions of Defendant HRC Medical’s BHRT contract or “Consent to Treat” form, Defendant HRC Medical states the following:

I, _____, waive the opportunity to submit documentation of having a Pap smear or Mammogram in the last year. By doing so, I give HRC Medical permission to begin Bio-identical Hormone Replacement therapy. I release HRC Medical and the practicing physician of *any liability or claim of malpractice due to any breast cancer* or cervical cancer. (emphasis added)

497. If asked about the contradiction between Defendant HRC Medical’s breast cancer protection claims and the purported malpractice waiver, sales consultants at Defendant HRC Medical were specifically instructed to state that Defendant HRC Medical’s BHRT protects against breast cancer and that the provision was needed to protect the company for existing breast cancers that occurred prior to initiation of BHRT.

498. In a later version of Defendant HRC Medical's contract, Defendant HRC Medical states the following, albeit neither clearly nor conspicuously, and after a description of numerous purported benefits in advertisements and a sales presentation emphasizing the therapy's safety:

I realize that there are potential concerns with testosterone therapy, and they include the possibility of enhancing a current prostate cancer to grow more rapidly. For this reason, a prostate specific antigen blood test is to be done before starting testosterone and will be conducted each year thereafter. If there is any question about possible prostate cancer, I consent to follow-up with an ultrasound of the prostate gland.

The second concern we have with testosterone therapy is that it may increase one's hemoglobin and hematocrit or thicken one's blood. This can be reversed through donating blood periodically. This problem can be diagnosed with a blood test. Thus, a complete blood count should be done at least annually. One CBC may be done each year.

499. An increase in hemoglobin, hematocrit, or the "thickening" of one's blood, as described, albeit inconspicuously and incompletely in Defendant HRC Medical's contract, may increase the risk of developing a blood clot, stroke, heart attack, or other cardiovascular problems.

500. Defendants, in any of their advertisements for Defendant HRC Medical's BHRT have never clearly and conspicuously disclosed an increased risk of prostate cancer, an increased risk of blood clots, strokes, or other cardiovascular problems that can come from increased hematocrit levels or increased blood "thickness" as referenced albeit inconspicuously and incompletely in Defendant HRC Medical's contract.

501. Additionally, Defendants have not clearly and conspicuously disclosed that Defendant HRC Medical's BHRT may:

- In women, cause a permanent enlargement of the clitoris, which can be extremely uncomfortable and make wearing pants painful.
- In men, cause testicular atrophy, impotency, and the development of breast tissue similar in appearance to that found in women;

- In men, cause a cascading effect on the hormone production centers within a man's body, which can ultimately result in the end of a man's ability to produce his own testosterone;
- In both men and women, lead to loss of hair on one's head, voice deepening, acne, and growth of permanent hair on one's face, chest, buttocks and other undesirable places on the body;
- Cause menstrual or menstrual-like bleeding in menopausal women;
- In both men and women, lead to psychological changes such as increased anger or aggressive behavior.

502. Defendants have not disclosed, clearly and conspicuously or otherwise, that Defendant HRC Medical's BHRT may cause one to gain weight; rather Defendant HRC Medical and Defendant Dan Hale, on behalf of Defendant HRC Medical, have stated the opposite, namely that Defendant HRC Medical's BHRT causes weight loss or better weight control.

503. After taking Defendant HRC Medical's BHRT, consumers in Tennessee have experienced significant clitoral swelling, heart palpitations and chest pains, high blood pressure, loss of hair on the top of their head, voice changes, growth of hair on the face, chest, arms, and stomach, severe headaches, mood changes, and severe acne.

504. In the limited instances in which Defendants do reference side effects, Defendants omit reference to the most serious side effects or risks, significantly understate the few cosmetic side effects they do disclose, frame the few cosmetic side effects they do disclose as an unfounded superiority claim over traditional HRT, falsely state the side effect is temporary, or falsely present the side effects as being a positive change.

505. For example, in a brochure for its BHRT, excerpted below as Figure 22, distributed to prospective consumers in Tennessee, Defendant HRC Medical only stated the following about side effects:

What are the side effects?

A small number of women may have increased breast sensitivity and spotting. The spotting is managed with progesterone capsules each evening. Most of these side effects, if they occur, will resolve after your body adjusts to the hormones.

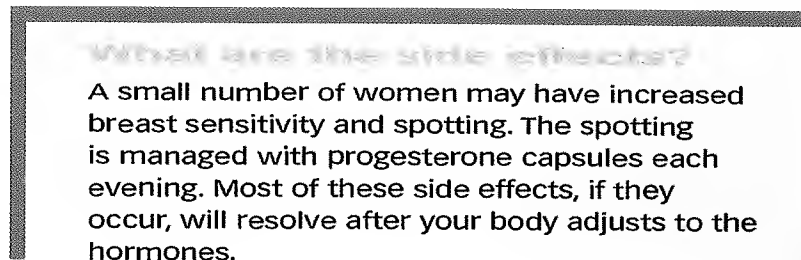


Figure 22 (Not to Scale)

506. Prior to a change to remote portions of Defendant HRC Medical's website in April 2012, some seven years after the company's founding, the *closest* that Defendant HRC Medical ever got to the full disclosure of side effects was in its contract, which was given to consumers *after* seeing any advertisements or hearing any sales pitch for BHRT from a sales consultant who was paid on a 100% or partial commission basis.

507. Prior to 2009, Defendant HRC Medical did not make any side effect disclosures whatsoever in documents given prior to the point of sale. At the time, Defendant HRC Medical's contract was a one page document without any side effect disclosures.

508. Defendant HRC Medical eventually changed its contractual agreement. More recently, Defendant HRC Medical has had consumers sign either a male or female version of "Hormone Replacement Therapy Agreement Form."

509. The female version of the form, current at least as of August 2011, states the following, in relevant part:

I realize that testosterone can increase my energy, my libido, and increase my sense of well-being. I may also see testosterone decreasing the frequency and severity of my headaches. I have also been told that I am to have bio-equivalent hormonal estrogen inserted under my skin to achieve a steady stage of estrogen in my body.

I realize that estrogen can eliminate my mood swings, anxiety and irritability.

I realize that in the past, male athletes have abused testosterone. When they took huge quantities of synthetic testosterone, they may have incurred heart problems and elevated cholesterol. *However, low-dose, non-oral, natural testosterone that is used in bio-equivalent hormonal therapy has NOT been associated with these problems. . .* I understand that possible side effects from Estrogen may include: breast tenderness, irregularities of the menstrual cycle or recurrence and temporary water retention. I understand that possible side effects from Testosterone include: facial hair growth, skin irregularities, and an increase in sex drive. (emphasis added)

510. In contradiction to many other statements made by Defendants about BHRT, Defendant HRC Medical has recently updated *remote* portions of its website to reference some side effects of its BHRT. This update, which the State asserts is still inadequate, has occurred nearly seven years after Defendant HRC Medical's founding and after the company has claimed to provide its BHRT to 30,000 people nationwide.

511. Even if the consumer can find the references to side effects on remote portions of Defendant HRC Medical's website, which is far from a given, these references do not mention the most serious risks and side effects associated with Defendant HRC Medical's BHRT, are contradicted by Defendants' other express marketing claims about Defendant HRC Medical's BHRT, are surrounded by misinformation about the relative safety of Defendant HRC Medical's BHRT, are false, are deceptive, or are otherwise not accurately conveyed clearly and conspicuously to the consumer.

512. Further, as if to underscore the lack of importance given to Defendant HRC Medical's references to side effects, the remote side effect pages themselves are riddled with basic grammatical errors and spelling mistakes—including repeated misspellings of Amor Vie, the name for Defendant HRC Medical's brand of BHRT—that would have been caught with even a cursory reading of the page.

513. As currently configured, a viewer of www.hrcmedical.com must navigate through Defendant HRC Medical's efficacy, benefit, and safety claims about its BHRT and then undertake a series of deliberate steps before getting to the first page about side effects.

514. If a consumer is able to find it, the overview page of side effects on Defendant HRC Medical's website states the following set out in gray:

Like virtually every other medical treatment, procedure or prescription medication, that is designed to improve your well being, bioavailable Natural Hormone Replacement Therapy (bioNHRT) affects how your body functions so you can realize improvement in the areas desired and may have a few side effects or carry some small risks for a very small percentage of patients. You need to have a thorough understanding of them to evaluate the therapy for yourself.

But, unlike many other medical treatments, procedure [sic], or prescription medication [sic], the Natural Bio-Available Hormones used in HRC's AMORE [sic] VIE therapy are naturally derived (from the Yam plant). Being naturally derived, they work almost identically to those hormones already existing in the human body without the introduction of any synthetic matter that greatly change [sic] the risk factor evaluation.

Additionally, the foundation of the AMOR VIE therapy is built on a process that frequently monitors the patient. Through this monitoring we can bring the patient to the desired hormone levels at a gradual pace consistent with the patients [sic] base line and desires. We start with a consultation, blood screening, a detailed history of symptoms relative to possible hormone deficiency, and a physical exam by our medical staff. This is followed by a tailored dosing plan before any procedure is deployed [sic] which by the way is virtually painless. Importantly [sic] we routinely check blood levels throughout the year and adjust future dosing accordingly.

It is important to note that almost all of the side effects that might be experienced can be adjusted dosing related [sic] in that if side effects are felt a simple reduction of dosing will generally reverse the affect. Many reported issues actually relate to the reduction of prescribed levels if the patient spaces treatment farther apart then recommended.

Finally, and perhaps most importantly, every person is unique. The AMOR VIE therapy is designed specifically for your unique needs. Consequently, RESULTS MAY VARY. If you experience any side effect that you believe requires discussion with our staff you should contact them as soon as possible so we can assist you in making what ever [sic] adjustments are necessary to help you. . . . Restore, Renew, and Rejoice. (emphasis added)

515. On the second page in, entitled "Mitigate Side Effects," Defendant HRC Medical states the following set forth in gray below:

Most of the side effects can be reduced or eliminated with adjustments in dosing that [sic] if side effects are felt a simple reduction of dosing will generally reverse the affect. Ironically, many issues reported by patients actually relate to the reduction of prescribed levels if the patient spaces treatment farther apart then recommended. The following is a brief summary of some of the key attributes of the AMOR VIE therapy that significantly enhance the benefits and greatly reduce any risk of the therapy.

- The AMOR VIE Therapy uses "Bio Natural/Bio Available" Hormone [sic] replacement compounded to mirror the hormones naturally produced in the human body. *This eliminates the risk of synthetic hormones that have received much attention over the last several decades.* The Hormone [sic] formulations have been in use since the 1930's.
- The compounding of our Hormones [sic] is performed in a highly controlled sterile environment at one of the most advanced compounding pharmacies in the country who [sic] is among a select group of compounding pharmacies who [sic] is accredited by the Pharmacy Compounding Accreditation Board (PCAB).
- In all cases, each procedure is dosed and specifically tailored to each patient by a doctor after a though [sic] blood screening using the knowledge created through over 30,000 patient experiences.
- Generally all "side effects" are "Dose Related" to our 3 major Natural Hormones (Testosterone, Progesterone, Estrogen). These effects can generally be easily controlled through dosing adjustments.
- *The side effects are generally minor. Most are cosmetic or temporary.*

- Many of our patients have found that with the guidance of their Primary Care Physician (PCP), that they are able to reduce or eliminate some of their existing prescription medication upon the initiation of the AMOR VIE therapy. Often these medication are used to treat the effects of underlying pathologies that a return to one's prime hormone levels Through [sic] AMORE [sic] VIE's therapy can eliminate, importantly these medications often carry with them significant risks, generally viewed to be far more potentially serious than NHRT. We have include [sic] some of our patient stories explaining this phenomena in the section of our website.

- *In very few situations [sic] a patient can experience an elevation of Blood [sic] pressure, which is generally considered the most serious "side effect". This should immediately be reported to your PCP and us. This effect is easily diagnosed & treated with routine monitoring.*

- *We have never had a life threatening issue with any of our 30,000 patients.*

- *Of 900+ customer satisfaction "stories" included in our website, a few mention side effects. All were minor and generally eliminated or reversed over time. We have included these patient stories here in our website to illustrate how others have experienced the AMOR VIE therapy to help you make an informed decision.*

- Our 1 year therapy program is designed to provide close over sight so adjustments can be made as needed based on, frequent blood draws (approximately once per quarter), on line monitoring, and close oversight by medical staff.

- We have a 97% satisfaction rating (Approximately 3% refund rate due to dissatisfaction of results).

- Patients can generally weigh their own tolerance for the side effects & choose levels of desired risk/benefits based on their personal desire. This can be altered with each visit depending on their lab results, doctor guidance, and personal feedback.

- We do only Hormone treatment. That is our specialty. This gives us unique insight and capability based on our size & specialty. Each Medical [sic] staff is fully trained. The medical staff sees all patients before treatment is started.

- Because of the individuality and complexities of the Human Body [sic] RESULTS WILL VARY as our therapy is designed to tailor [sic] to your individuality.

We also have a suite of "supplements" that greatly helps extend our treatment or helps the patient improve their symptoms proactively. Never-the-less [sic] there are some effects that some patients have reported as summarized in the following sections. We

are including a brief description of each effect and cause along with our common response to alleviate or treat the symptom. Also for your convenience we have included a table summarizing these effects on a separate tab. (emphasis added)

516. On its "Affects [sic] and Side Effects Female" subpage, Defendant HRC Medical states the following set forth in gray below:

Most side effects of estradiol and testosterone are actually caused by the way they function naturally. The emphasis here is "naturally". *Some of the side effects often associated with estradiol or testosterone as seen in the literature are not applicable to bioavailable Natural Hormone Replacement Therapy (NHRT) and HRC's AMOR VIE therapy program for two important distinctions: 1. The method of delivery and 2. The source of the hormone.*

1. Method of Delivery The AMOR VIE NBHRT is delivered in pellet form subcutaneously (a small pellet usually smaller than a grain of rice for women and slightly larger for men is placed under the skin in the upper outer quadrant of the buttocks). This truly delivers the dosing at a constant even rate over a 2-3 month interval when the body requires it (hence the term Bio-Available). Just as importantly it is not processed through the liver as first pass metabolism. Many other programs deliver the hormone either orally, through shots, patches, or creams, which may have unwanted consequences. For example, when any estrogen is given by mouth (a pill) it has a much greater risk of more severe symptoms such as strokes, heart attacks, and blood clots.

2. Source of Medication When estradiol is given with progestin, especially orally-(i.e. such as Provera which is a synthetic drug and not natural), there is a risk of thromboembolism and breast cancer. Synthetically derived Testosterone or estrogen has a number of known clotting and liver related side effects.

When HRC's Naturally [sic] derived and subcutaneously delivered painlessly [sic] therapy these liver first-pass side effects are not seen.

However, there are some side effects that may be experienced (by a very few of our patients). They are:

Possible Estradiol Side Effects in the Female

Tender Breasts: Estradiol re-introduced to the menopausal patient may cause temporary tenderness of the breasts. The breasts are normally stimulated regularly in a young female by estradiol. Without estradiol the breast begin [sic] to sag and become smaller. Additionally, they are not as supple and sensitive to stimulation. With estradiol the breast may enlarge slightly and become tender until becoming accustomed to an increase in estradiol. If one develops tender breasts the treatment usually is to take a NSAID (non-steroidal anti-inflammatory drug) for a few days and apply Oil of Evening Primrose twice a day. *However, this treatment is usually not necessary as the soreness, if any, is short-lived.*

Fluid retention: As is well known, when estrogen increases one can retain some fluid as may be seen with each cycle sometime [sic] causing an increase in 2 or 3 pounds on

the scales. *This is normal and expected. When natural estradiol is given there can be some temporary edema until the body adjusts. If it is necessary a mild diuretic may be given for 3 or 4 days to reduce the swelling.*

Occasional Uterine Bleeding: Some bleeding/spotting may occur when not expected in a female that is menopausal, or perimenopause with estradiol therapy. *This side effect is usually easily resolved by increasing the progesterone dose.* Progesterone is the hormone that acts to control the effects of estradiol. The reason for uterine bleeding in a perimenopausal or menopausal female is that the uterus dries up naturally from lack of the natural hormone, estradiol. When estradiol is re-introduced the uterus can once again resemble a uterus of a young healthy female. However, when sufficient progesterone is given uterine bleeding can be stopped. Progesterone should be given to women who have a uterus and are treated with estradiol. If one takes progesterone daily there is usually no spotting or abnormal bleeding. If one is still cycling and wants to continue she can take progesterone 15 days each month and still have regular periods.

Possible Testosterone Side Effects in the Female:

Testosterone replacement in women is often not performed by some who perform BHRT. However, it is important to remember that the ovaries normally produce all three important hormones; testosterone, progesterone, and estradiol. *It is unfortunate that many other providers replace only the latter two hormones. Women need testosterone, but obviously at a much lower dose than a man.* When a female patient is dosed, it is frequently necessary to adjust her testosterone according to her response, as we prefer to start with a lower dosage and increase based on her comfort level. The impact of testosterone replacement in women is often fairly immediate (generally within a week or ten days).

The following side effects related to testosterone can be experienced in a small percentage of female patients:

Minor Facial Hair Growth: Excess testosterone from a hormone replacement therapy is often "blamed" as the primary "culprit" for excess hair growth in menopausal aged women. It is true that the appearance of minor facial hair is not an unusual side effect (for a few) when testosterone is high in women. *However, and this is a big HOWEVER, the real root cause is often overlooked. The growth of minor facial hair, at some level, depending on the predisposition of the women, is a normal effect of the loss of estrogen as women face menopause. The "irony" of the effect is that the loss of estrogen (which is the hormone that suppresses the growth of hair on the face) will, if left unchecked, cause facial hair growth anyway if the women is predisposed to that phenomenon. So the linkage is often made to testosterone because the introduction of this in a hormone replacement therapy happens at the same time in life as their normal loss of estrogen. It is highly likely they would have experienced this phenomena anyway.* There are a number of natural remedies (as discussed below) that can help address this normal phenomenon. This subject is covered very thoroughly in a book, *The Savvy Woman's Guide to Testosterone* by Elizabeth Lee Vliet, M.D. She says, "Paradoxically, androgens (testosterone) have different effects on hair follicles

depending on where they are on the body: they can stimulate growth of thick coarse dark hairs on the face, chin, back, arms, pubic area, or inner thighs; they can inhibit scalp hair follicles. It is a great mystery in endocrinology how an excess of a hormone can cause excess hair growth just as a lack of the same hormone can cause hair loss. (Interestingly enough, our patients occasionally have expressed the same paradox as if one reads the stories included in this section, some patients have expressed how NHRT has been of significant benefit in thickening their thinning hair when hormone levels were too low while a few others have sited [sic] some appearance of facial hair especially in the treatment until levels were balanced). *The excess facial and body hair that is more coarse and dark than the person's natural color, especially if estradiol is also too low.* When excess facial hair is seen a dosage reduction of testosterone may be in order. If one has more facial hair than is tolerated [sic] a topical treatment, Vaniqua, can be recommended. Also laser hair removal can be beneficial.

Minor Receding of Scalp Hair: Minor scalp hair loss is possible with high testosterone in a female. Dr Vilet again covers the subject of hair loss in females suggesting that testosterone deficiency also can cause loss of scalp hair as well as low estradiol. It is possible to experience some growth of hair on parts of the body while at the same time seeing signs of some scalp hair loss. *If estradiol levels are too low when testosterone is too high this can accentuate scalp hair loss.* This is why the close monitoring of hormones in our routine blood work is critical to monitoring appropriate levels. When one experiences loss of testosterone, especially if sudden as seen with removal of the ovaries, thinning of the scalp and body hair can be experienced. Loss of scalp hair should be reported to the medical staff for treatment. We have found that if there is some loss of scalp hair it generally is not a permanent condition. For temporary hair loss it is recommended that one use Rogaine Foam 5% twice a day for a month or 2. Also topical progesterone drops can be used twice a day.

Minor Acne: Acne resulting from testosterone supplementation is more common in women than in men. With conservative treatment [sic] acne is not a significant problem in a large majority of female patients. Acne occurs from an increase activity of the sweat glands especially on the face as the natural oils in the skin are replaced (which paradoxically also helps return the skin to a more youthful appearance). If acne does occur it is easily treated when the medical staff is notified. A topical antibiotic cream is frequently prescribed as well as a medication to block the effect of testosterone on sweat glands. Occasionally an oral antibiotic is necessary. It is interesting to note that Menopausal [sic] women often resort to using cosmetics and body lotions that are designed to restore lost oils and skin moisture. Emollients are used. These Emollients [sic] can amplify the oils created by the testosterone and further act to clog up pores resulting in acne breakouts. It is suggested that women on T2 Therapy use "Oil Free" products and make-up must [sic] the same as teens and younger women do.

Hypertension: An elevation in blood pressure secondary to testosterone treatment is very rare; however, when it does occur this must be reported to the medical staff.

Testosterone usually functions as a vasodilator (opens up blood vessels) but in unusual circumstances salt retention may occur and blood pressure may rise. This side effect is usually easily treated with a diuretic or referral to your PCP (Primary Care Physician).

Deepening of the Voice: Voice changes in the female patient is one of the least often seen with testosterone treatment; however, it can be bothersome to some when it does occur, especially if the patient sings or has to talk a lot in her employment. *Deepening of the voice usually resolves spontaneously with changing the dosage of testosterone given; however, this may require 6 to 9 months or longer in very unusual cases.* There is no known treatment when deepening of the voice occurs except to temporarily discontinue treatment until the voice changes and then begin [sic] treatment with testosterone again, but at a lower dosage.

Clitoral Enlargement: Clitoral enlargement is rare with testosterone therapy. Additionally, a slightly enlarging clitoris is often thought of as a positive effect as clitoral stimulation is easier with intercourse. Enlargement beyond this is seen only with excess testosterone typically associated with sex-change surgery. *Excess testosterone is not dosed at HRC Medical therefore treatment for clitoral enlargement is not seen to a degree requiring treatment.*

Awareness & Interaction With Other Medications:

At the outset on menopause (women) and andropause (men), symptoms of depression may develop. These symptoms can be brought on by the depletion of our essential hormones as we age. All too often, medicine overlooks the correlation between depleted hormones and symptoms of depression and in an effort to alleviate suffering, the physician may prescribe an antidepressant to address the symptoms. While these drugs effectively combat the "lows" of depression, they also eliminate the "highs" we can feel in experiencing the joys of life. While hormone restoration can often reverse the symptoms of depression, in these cases continued use of antidepressants is counter-productive and can interfere with the beneficial effects of restoration. When a person has been under antidepressant therapy for any length of time, it becomes necessary to carefully wean the patient from the antidepressant therapy for any length of time, it becomes necessary to carefully wean the patient from the antidepressant with the cooperation and under the care of their prescribing physician to fully realize the benefits of hormone restoration. Similarly, for those who experience constant pain, such as joint pain, fibromyalgia or migraines, the physician may prescribe analgesics (pain killers) to varying degrees and of varying strengths. These drugs, too, act in a similar way to "block" certain nerve impulses. This blocking action can interfere with the beneficial and natural anti-inflammatory effects of hormone restoration. In these cases as well, we will work closely with the prescribing physician to carefully wean the patient, when appropriate, to enable the restored hormones to re-balance.

Awareness of Possible Contraindications:

Bioavailable Natural Hormone Replacement Therapy (NHRT) is the natural way to restore hormones lost over time with age. However, there are times when bioavailable NHRT may not be immediately indicated.

Those that have been diagnosed with and treated for certain cancers should be 2 years or more in remission before initializing bioavailable NHRT. In some instances, depending on the type and stage of the cancer battled, a longer remission time may be considered.

Those with a baseline laboratory result of 4 or higher on a PSA (prostate specific antigen) should first confirm that the elevated PSA is not the result of prostatic cancer. While recent studies suggest that testosterone does not cause cancer (it has been suggested that low testosterone may actually lead to the development of certain prostatic cancers) a prostate cancer in concert with low blood levels of testosterone may actually grow when testosterone is newly introduced until the prostate is "saturated" with testosterone at which point the cancer growth appears to cease.

Those that are pregnant or nursing.

If you experience any of the side effect, or others, in your treatment you should immediately discuss them with your HRC medical staff. If they persist or become more severe you need to discuss with your PCP (Primary Care Provider). (emphasis added)

517. On its "Affects [sic] and Side Effects Male" subpage, Defendant HRC Medical states the following set forth below in gray:

Most side effects of testosterone are actually caused by the way they function naturally. The emphasis here is "naturally". Some of the side effects often associated with testosterone as seen in the literature are not applicable to bioavailable Natural Hormone Replacement Therapy (NHRT) and HRC's AMOR VIE therapy program for two very important distinctions: 1. The method of delivery and 2. The source of the medication

1. Method of Delivery The AMOR VIE NHRT is delivered in pellet form subcutaneously (a small pellet usually smaller than a grain of rice for women and slightly larger for men is placed under the skin in the upper outside quadrant of the buttocks). This truly delivers the dosing at a constant even rate over a 2-3 month interval when the body requires it (hence the term Bio-Available). Just as importantly it is not processed through the liver as first pass metabolism. Many other programs deliver the hormone either orally, through shots, patches, or creams, which may have unwanted consequences.

2. Source of Medication *Synthetically derived Testosterone has a number of known clotting and liver related side effects. HRC uses only naturally produced Testosterone (Derived from the Yam plant).*

With HRC's Naturally derived and subcutaneously delivered therapy these side effects are not seen.

However, there are some side effects that may be experienced (by very few of our patients). They are:

Possible Side Effects of Testosterone Therapy in Men:

Men usually require up to 10 times the level of testosterone as women. However, men do not need estrogen replacement. After age 30 [sic] most men will begin a gradual decline in testosterone with inevitable negative results including loss of muscle mass, fatigue, loss of energy, weight gain, mental foginess, possible depression and even possible erectile dysfunction. *With NBHRT [sic] our experience is that most men will see many or all of the testosterone deficiency signs disappear. Many have told us they feel as if they have regained their "mojo" (See the stories in this section submitted to us by many of our patients that discuss these effects on them.)*

The following side effects related to testosterone can be experienced in a small percentage of our male patients:

Minor Acne: It is possible a male patient may see some acne generally on his chest and back especially if the patient experience severe acne as a teenager. This is very unusual and easily treated when reported to the medical staff.

Testicular Atrophy: When testosterone begins to decline in a male, usually after age 30, the brain senses this drop and uses a hormone, luteinizing hormone (LH), to stimulate the testicles to begin producing more testosterone. *This may cause the testicles to increase in size very slightly (to enlarge – hypertrophy). This change is almost never noticed without careful measurements, as it is generally very minor. When the patient who has hypertrophy of the testicles receives testosterone therapy the testicles may reduce in size, (again-this is very minor) but this is usually seen as a return to the "normal size" they were before testosterone began to decline. When testosterone is deficient for many years, as is seen in the aged, the testicles begin to shrink (atrophy).*

Erythrocytosis: *Testosterone is a source of stimulation of the production of red blood cells (RBCs). This is a good thing.* It keeps us healthy. Without sufficient testosterone one may become anemic. When testosterone is given to a male (and rarely to a female) it may cause an over production of RBCs. This is why at HRC Medical your blood is frequently checked to make sure you do not have erythrocytosis developing. If it is discovered that you have too many RBCs you may be asked to donate a unit of blood.

Decreased Sperm Count: Testosterone treatment will usually decrease the sperm count. *While usually the reduction in sperm count is modest, it can be significant in some, sometimes as much as 95%.* This is important to a male who is anticipating fathering a child. If this is a possibility, you should have your sperm frozen. *You can also get off of testosterone supplementation for 5 or 6 months and usually your sperm count will return to sufficient levels to father a child.* However, if you have been on testosterone therapy for an extended time (while the exact time varies from person to person it is usually assumed to be more than 5 years) the testicles may stop production of sperm permanently.

Hypertension: *An elevation in blood pressure is very unusual resulting from testosterone therapy as testosterone is a vasodilator (opens up blood vessels).* If your blood pressure is elevated the medical department must be notified. This elevation is more likely to occur when one has had hypertension in the past. This is why your

blood pressure is checked with each visit to assure you are safe. This side effect is usually easily treated with a diuretic or referral to your PCP (Primary Care Physician). (See the stories in this section submitted to us by many of our patients that discuss these effects on them) [sic]

Awareness & Interaction With Other Medications:

At the onset of menopause (women) and andropause (men), symptoms of depression may develop. These symptoms can be brought on by the depletion of our essential hormones as we age. All too often, medicine overlooks the correlation between depleted hormones and symptoms of depression and in an effort to alleviate suffering, the physician may prescribe an antidepressant to address the symptoms. While these drugs effectively combat the "lows" of depression, they also eliminate the "highs" we can feel in experiencing the joys of life. While hormone restoration can often reverse the symptoms of depression, in these cases continued use of antidepressants is counter-productive and can interfere with the beneficial effects of restoration. When a person has been under antidepressant therapy for any length of time, it becomes necessary to carefully wean the patient from the antidepressant with the cooperation and under the care of their prescribing physician to fully realize the benefits of hormone restoration. Similarly, for those who experience constant pain, such as joint pain, fibromyalgia or migraines, the physician may prescribe analgesics (pain killers) to varying degrees and of varying strengths. These drugs, too, act in a similar way to "block" [sic] certain nerve impulses. This blocking action can interfere with the beneficial and natural anti-inflammatory effects of hormone restoration. In these cases as well, we will work closely with the prescribing physician to carefully wean the patient, when appropriate, to enable the restored hormones to re-balance.

Awareness of Possible Contraindications:

Bioavailable Natural Hormone Replacement Therapy (NHRT) is the natural way to restore hormones lost over time with age. However, there are times when bioavailable NHRT may not be immediately indicated. Those that have been diagnosed with and treated for certain cancers should be 2 years or more in remission before initiating bioavailable NHRT. In some instances, depending on the type and stage of the cancer battled, a longer remission time may be considered. Those with a baseline laboratory result of 4 or higher on a PSA (prostate specific antigen) should first confirm that the elevated PSA is not the result of a prostatic cancer. While recent studies suggest that testosterone itself does not cause cancer (it has been suggested that low testosterone may actually lead to the development of certain prostatic cancers), a prostate cancer in concert with low blood levels of testosterone may actually grow when testosterone is newly introduced until the prostate is "saturated" with testosterone at which point the cancer growth appears to cease.

If you experience any of the side effects, or others, in your treatment you should immediately discuss them with your HRC medical staff. If they persist or become more severe you may need to discuss with your PCP (Primary Care Provider). (emphasis added)

518. The above omissions have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely as to the existence of, seriousness of, or extent of side effects and risks associated with Defendant HRC Medical's BHRT.

MATERIAL OMISSIONS IN CONSUMER TESTIMONIALS

519. In advertisements for its BHRT, Defendant HRC Medical has repeatedly used consumer testimonials from principals of the company, family members of the principals of the company, employees of the company, or others with a material connection to Defendant HRC Medical, all without clearly and conspicuously disclosing the relationship between the individual and Defendant HRC Medical.

520. In one advertisement for Defendant HRC Medical's BHRT directed towards consumers in Middle Tennessee, excerpted below as a screen shot as Figure 23, Defendant Don Hale, one of the founders of Defendant HRC Medical and its President and CEO, gives a consumer testimonial without any disclosure, clear and conspicuous or otherwise, of his ownership interest or other connection to Defendant HRC Medical.



Fig. 23 (Not to Scale)

521. In the same advertisement for Defendant HRC Medical's BHRT, excerpted below as a screen shot in Figure 24, Trina Lonning, the unlicensed medical assistant who was employed by Defendant HRC Medical at the time the advertisement was created, gives a consumer testimonial without any disclosure, clear and conspicuous or otherwise, of her connection to Defendant HRC Medical.



Fig. 24 (Not to Scale)

522. Another advertisement for Defendant HRC Medical's BHRT, excerpted below in a screen shot in Figure 25, aired on WSMV and featured Defendant HRC Medical employee Trina Lonning, without any disclosure, clear and conspicuous or otherwise, about her connection to Defendant HRC Medical featured the following statement:

JENNIFER HERRON: *Trina took things into her own hands and looked on the Internet for answers.* She wanted to be herself again. The person she was 20 years ago. . . . First she had to find out why the synthetic hormones she was taking only helped the hot flashes (emphasis added).

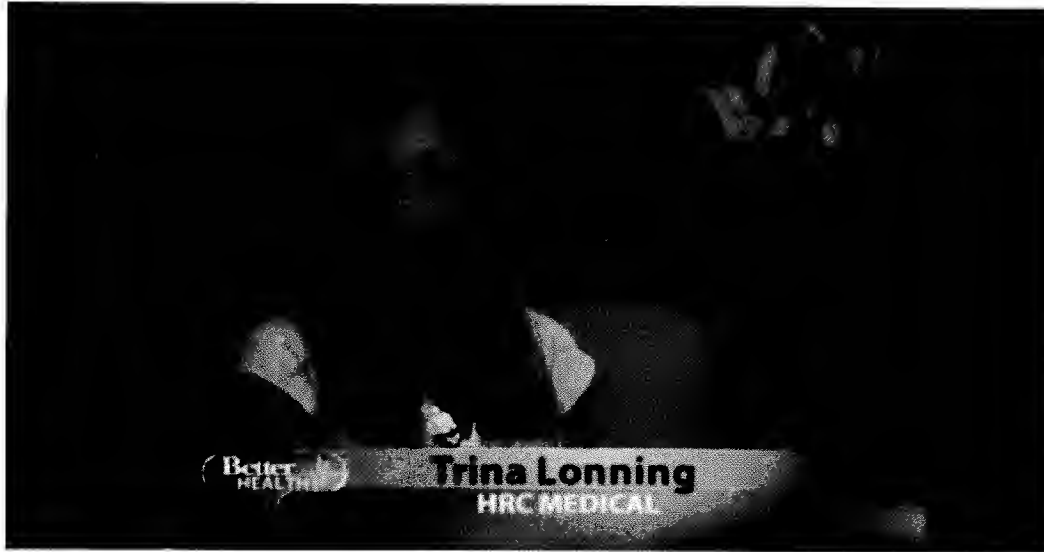


Fig. 25 (Not to Scale)

523. Similarly, in a different advertisement for Defendant HRC Medical's BHRT directed at consumers in Middle Tennessee and featured on Defendant HRC Medical's Facebook page for its Nashville office, excerpted below as screen shots in Figures 26, 27 and 28, Defendant HRC Medical features Don Hale, founder of Defendant HRC Medical, Defendant Don Hale's son, Drew Hale, and, Defendant Don Hale's daughter-in-law and Defendant HRC Medical Center employee Jennifer Hale, in consumer testimonials about Defendant HRC Medical's BHRT without any disclosure, clear and conspicuous or otherwise, about their respective connections to Defendant HRC Medical.



Fig. 26 (Not to Scale)

524. As shown in the excerpted screen shots in Figures 27 and 28 below, Drew Hale and Jennifer Hale speak while a statement states “Actual Bio-Identical Hormone Replacement Patient” appears on the screen.



Fig. 27 (Not to Scale)



Fig. 28 (Not to Scale)

525. Despite the fact that he is related by blood to the principals of the company and has been employed with Defendant HRC Medical, in an advertising capacity, Drew Hale states the following in this advertisement for Defendant HRC Medical’s BHRT:

I stumbled across the all-natural hormone replacement and I’ve been doing it and it’s been great. (emphasis added)

526. Similarly, Jennifer Hale, despite the fact that she is employed by Defendant HRC Medical, states the following:

I’m Jennifer. I’m 25 years old. I’ve been suffering from migraine headaches for as long as I can remember. Heard about the natural hormone replacement, so I got tested for it. And not only has it helped me with my migraine headaches, it has helped me with my energy level – I feel wonderful throughout the day. I sleep really well. I’m focused. And now I realize that it’s not only for women going through menopause, so I’m very happy that I did it. (emphasis added)

527. In the same advertisement for Defendant HRC Medical's BHRT that has been featured on Defendant HRC Medical's Facebook page for its Nashville office, one of the Nashville office's receptionists is depicted, as excerpted below in a screen shot in Figure 29, without any disclosure, clear or conspicuous or otherwise, about her status as an HRC employee.



Fig. 29 (Not to Scale)

528. In another television advertisement, excerpted in a screen shot as Figure 30, the woman who cleans Defendant Don Hale's home is featured in a consumer testimonial in an advertisement displayed on Defendant HRC Medical's Facebook page for its Nashville office without any disclosure of her financial relationship with one of the principals of the company.



Fig. 30
(Not to Scale)

529. Elsewhere, Defendant HRC Medical has used advertisements featuring HRC franchise owners Laura and Frank Mucerino, in consumer testimonials, as evidenced by the screen shot shown in Figure 31 below, that have run on multiple occasions on WSMV and that have not disclosed, clearly and conspicuously, or otherwise, the Mucerinos' franchise ownership and employment relationship with Defendant HRC Medical.

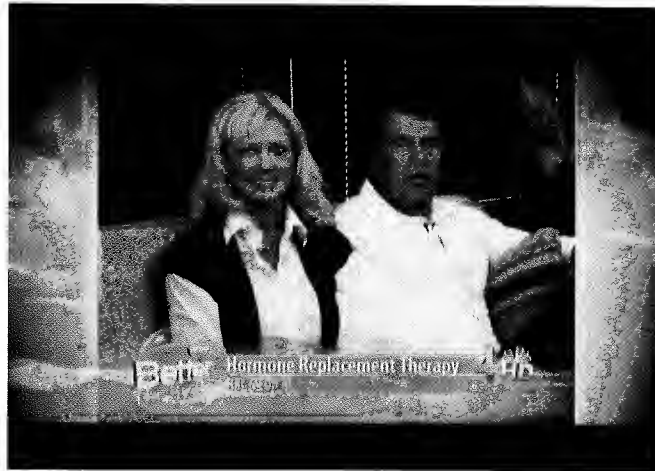


Fig. 31 (Not to Scale, Image Cropped).

530. In one advertisement for Defendant HRC Medical's BHRT on WSMV, the Mucerinos implicitly represent that they are neutral, third parties. Frank Mucerino states the following:

FRANK MUCERINO: From the day we walked in everybody's treated us like family. Really, just to tell the truth about it . . . so if you are going to get the therapy, this is what *they* do for a living it's not some doctor doing it on the side. . .

JENNIFER HERRON: Frank and Laura drive an hour to get their treatments at HRC and *that's in between running four businesses.* (emphasis added)

531. Laura and Frank Mucerino were owners of HRC Medical offices located in Overton Park, Kansas, Omaha, Nebraska, and formerly owned the Memphis office. The Mucerinos can be seen cutting the ribbon for their HRC Medical office in a photograph featured in an Overland Park

Chamber of Commerce newsletter excerpted below as Figure 32. The Mucerinos appear in the picture between Defendant Don Hale and Defendant Dan Hale.

Fig. 32
(Not to Scale)



Mayor Carl Gerlach, Chamber President Tracey Osborne and Chamber Diplomats helped Frank and Laura Mucerino, owners, and Mark Hamlin, manager, celebrate a ribbon cutting for HRC Medical, 7201 West 110th, Suite 120. HRC Medical uses natural hormone replacement therapy to treat symptoms of hormone imbalance. For more information: (913) 850-5700 or www.hrcmedical.com.

532. Frank Mucerino has been listed as the registered agent for HRC Medical Kansas, LLC.

533. Laura Mucerino signed the Kansas office's limited liability company documents filed with the Tennessee Secretary of State, one of which is excerpted below as Figure 33:


<p style="text-align: center;">State of Tennessee</p> <p style="text-align: center;"></p> <p>Department of State Corporate Filings 312 Rosa L. Parks Avenue 6th Floor, William R. Snodgrass Tower Nashville, TN 37243</p>	<p>APPLICATION FOR CERTIFICATE OF AUTHORITY (Limited Liability Company)</p>	<p style="text-align: right; font-size: small;">For Office Use Only</p> <p style="text-align: center; border: 1px solid black; padding: 2px;">RECEIVED</p> <p style="text-align: center;">STATE OF TENNESSEE</p> <p style="text-align: center; font-size: large;">2011 FEB -7 AM 11:34</p> <p style="text-align: center;">TRE HARGETT SECRETARY OF STATE</p>
<p>To the Secretary of State of the State of Tennessee:</p> <p>Pursuant to the provisions of §48-249-904 of the Tennessee Revised Limited Liability Company Act, the undersigned hereby applies for a certificate of authority to transact business in the State of Tennessee, and for that purpose sets forth:</p>		
<p>1. The name of the Limited Liability Company is: <u>HRC MEDICAL KANSAS, LLC</u></p> <p>If different, the name under which the certificate of authority is to be obtained is: _____</p>		

Fig. 33
(Not to Scale)
(Includes Page
Break)

[excerpt page break]

<p><u>February 7, 2011</u></p> <p>Signature Date</p> <p><u>Member</u></p> <p>Signer's Capacity</p>	<p><u>HRC Medical Kansas, LLC</u></p> <p>Name of Limited Liability Company</p> <p><u>Laura Mucervino</u></p> <p>Signature</p> <p><u>Laura Mucervino</u></p> <p>Name (typed or printed)</p>
<p>SS-4233 (Rev. 02/08) Filing Fee: \$50 per member / minimum fee=\$300, maximum fee=\$3,000 RDA 2458</p>	

534. Laura Mucervino has been employed by Defendant HRC Medical or one of its franchisees since at least by September 2010 as evidenced by her LinkedIn account below, which is excerpted as a screen shot in Figure 34:

Fig. 34
(Not to Scale)

Laura Mucerino

Bioidentical Hormone Replace Therapy at HRC Medical

Greater Nashville Area · Health, Wellness and Fitness

As a LinkedIn member, you'll join 150 million other professionals who are sharing connections, ideas, and opportunities. And it's free! You'll also be able to:

- See who you and **Laura Mucerino** know in common
- Get introduced to **Laura Mucerino**
- Contact **Laura Mucerino** directly

[View Full Profile](#)

Join LinkedIn and access **Laura Mucerino's** full profile.

Laura Mucerino's Overview

Current **Bioidentical Hormone Replace Therapy at HRC Medical**
Co-Owner at Pit Bull Family Enterprises

Education **Columbia State Community College**

Connections **20 connections**

Laura Mucerino's Experience

Bioidentical Hormone Replace Therapy **HRC Medical**

Privately Held; 11-50 employees · Health, Wellness and Fitness Industry
September 2010 – Present (1 year 10 months)

HRC Medical is the leading BHRT company in the country specializing in all natural plant based hormone replace therapy under the trade name of Amor Vie.

Co-Owner

Pit Bull Family Enterprises

October 2000 – Present (11 years 9 months)

Commercial Property Investment and Development

Laura Mucerino's Education

Columbia State Community College

Associates Degree, Nursing

Contact Laura for

535. Other consumer testimonials offered by Defendant HRC Medical show that the practice of getting individuals with close familial or financial ties to the company or its principals has been even more widespread. For example, Defendant HRC Medical features a consumer testimonial from Jenn Jackson on its Facebook account for its Nashville office, on its YouTube page, and on its website, www.hrcmedical.com, without disclosing that she is an advertising account executive for a North Carolina-based radio station on which Defendant HRC Medical advertises. An excerpt of Ms. Jackson's testimonial for Defendant HRC Medical's BHRT appears as a screen shot in Figure 35 below:



Fig. 35

536. Jenn Jackson's LinkedIn account is excerpted below as Figure 36:



Jenn Jackson

--
Charlotte, North Carolina Area · Broadcast Media

As a LinkedIn member, you'll join 150 million other professionals who are sharing connections, ideas, and opportunities. And it's free! You'll also be able to:

- See who you and **Jenn Jackson** know in common
- Get introduced to **Jenn Jackson**
- Contact **Jenn Jackson** directly

[View Full Profile](#)

Join LinkedIn and access Jenn Jackson's full profile.

Fig. 36
(Not to Scale)

Jenn Jackson's Overview



Current	Director of Affiliate Sales - "Bob & Sheri Show" at Greater Media Account Executive at WBT and WLNK Radio
Past	Account Executive at Clear Channel Radio
Education	University of North Carolina at Greensboro
Connections	193 connections
Websites	Company Website Company Website Company Website

Jenn Jackson's Experience

Director of Affiliate Sales - "Bob & Sheri Show" **Greater Media**

Private/Held: 501-1000 employees, Broadcast Media industry
August 2010 – Present (1 year 11 months) Charlotte, North Carolina Area

Account Executive **WBT and WLNK Radio**

Marketing and Advertising industry
2010 – Present (2 years)

Account Executive **Clear Channel Radio**

Public Company; 10,001+ employees, OSC, Broadcast Media industry
2000 – 2010 (10 years)

537. Defendant HRC Medical has advertised on the WLNK radio station. Further, a duplicate copy of Ms. Jackson's BHRT video testimonial for Defendant HRC Medical is posted under the YouTube handle "linkradio," which is the YouTube handle used by the WLNK radio station.

538. The ownership interest, family relationship, employment relationship, business relationship, and monetary relationship of individuals featured in testimonials affect the weight or credibility of the testimonial.

539. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that the consumers featured in advertisements have no material connection to Defendants, are unbiased, or are otherwise made at arm's length.

540. Defendant HRC Medical has compensated consumers through discounts on pellet treatments or other services and not disclosed this fact in advertisements featuring testimonials. A number of consumers, if not all of them, have received compensation in the form of "free" BHRT or discounted BHRT from Defendant HRC Medical in exchange for their testimonies, a fact which has not been disclosed, clearly and conspicuously or otherwise, in advertisements featuring these consumers.

541. As one example, Defendant HRC Medical featured several testimonials of a BHRT consumer named Carolyn Bigham. In exchange for her testimonial, Ms. Bigham received discounts or "free" BHRT pellet insertions. Screen shots of Defendant HRC Medical's BHRT advertisement featuring consumer testimonials of BHRT, without any disclosure, clear and conspicuous or otherwise, are excerpted below in screen shots as Figures 37 and 38:

Fig. 37
(Not to
Scale)



Fig. 38
(Not to Scale)



542. The compensation through discounts on future or current treatments featured in testimonials affects the weight or credibility of the testimonial.

543. The above statements and others of similar import have caused or tend to cause consumers to believe what is false or have misled or tend to mislead consumers as to a matter of fact, namely that the consumers featured in advertisements have no monetary connection to Defendants other than purchasing BHRT.

544. In fact, many advertisements featuring consumers for Defendant HRC Medical's BHRT state that the consumer is not being paid in exchange for their testimony.

545. Aside from the failure to disclose the benefit, Defendant HRC Medical, in the instances in which consumers received "free" or discounts off future or pending BHRT and Defendant HRC Medical stated that the consumer was not paid, misled consumers as to a matter of fact, namely that the consumers did not receive compensation or any benefit in exchange for their testimonial.

MATERIAL OMISSIONS OF CONSUMER SIDE EFFECTS IN TESTIMONIALS

546. Defendant HRC Medical has repeatedly used consumers, including employees of Defendant HRC Medical, in testimonials who have experienced side effects of its BHRT without disclosing the side effects that the consumers actually experienced after taking the therapy.

547. HRC Male Location Owner 1 (names have been withheld to protect health care privacy, but are identified to Defendants and the court through documents filed under seal), who appears in several advertisements for Defendant HRC Medical's BHRT in a consumer testimonial, developed very high hematocrit and hemoglobin levels, a condition that can lead to serious health risks.

548. HRC Male Employee 1, a younger man who appears in several advertisements for Defendant HRC Medical's BHRT in a consumer testimonial, stopped taking Defendant HRC Medical's BHRT after he was informed by a Defendant HRC Medical employee that Defendant HRC Medical's BHRT may cause infertility.

549. HRC Female Employee 1, who appears in several advertisements for Defendant HRC Medical's BHRT, actually stopped taking Defendant HRC Medical's BHRT after only *one* pellet implant because of endometriosis, a disorder that occurs when cells from the lining of the uterus grow in other areas of the body. Endometriosis can lead to pain, irregular bleeding, and infertility.

550. HRC Female Employee 2, who appears in several advertisements for Defendant HRC Medical's BHRT without any disclosure, had significant clitoral swelling as a result of taking the therapy, which she openly discussed with others at Defendant HRC Medical. HRC Female Employee 2 also has had to be on blood pressure medication.

551. HRC Female Employee 3, who appears in several advertisements for Defendant HRC Medical's BHRT stopped taking Defendant HRC Medical's BHRT after developing severe acne and facial hair.

552. HRC Female Employee 4, who appears in a couple of advertisements for Defendant HRC Medical's BHRT, without disclosure, experienced increased facial hair growth after taking Defendant HRC Medical's BHRT.

USE OF NO REFUND/STORE CREDIT POLICY

553. As discussed above, under Defendant HRC Medical's sales model for its BHRT, a consumer is first directed to a "free" consultation, where he or she speaks to a sales consultant, who usually has no medical training whatsoever and is paid on a 100% or part-commission basis. The "free" consultations are arranged based on a tiered appointment system in which the highest-performing sales representative has her calendar filled first. At the "free" consultation, the consumer is given a sales pitch about Defendant HRC Medical's BHRT, asked to fill out a broadly worded symptom questionnaire sheet (e.g. "sleep disturbances," "fatigue," "poor focus," and "memory lapses") and, if they checked even one vaguely worded symptom, is then asked, absent rare circumstances, to sign a non-refundable contract to purchase the therapy. The price of the therapy ranges from \$2,000 to \$4,000. The consumer leaves the "free" consultation having given blood for laboratory tests that will supposedly indicate whether the consumer is a candidate for BHRT, yet having already committed to and paid for a year's worth of Defendant HRC Medical's BHRT.

554. While Defendant HRC Medical offers the ability to purchase single pellet implants, both the pricing itself and the sales consultants who describe the pricing, as directed by Defendant Don Hale, strongly encourage consumers to pay for or finance one year's worth of Defendant HRC

Medical's BHRT in advance as a non-refundable lump sum. Defendants use this sales tactic without knowing whether the BHRT will be appropriate at that time, before blood levels are drawn, or how the consumer will respond to the therapy even initially.

555. Defendant HRC Medical has repeatedly used contractual agreements containing provisions stating that the lump sum amount, typically ranging between \$2,000 and \$4,000 and primarily used to pay for future hormone pellet implants, is non-refundable.

556. Aside from wanting to retain cash payments, Defendant HRC Medical is also incentivized to require non-refundable lump sums through the contractual agreements that it has entered with the financing companies it uses including GE CareCredit and Chase HealthAdvantage. The financing companies require Defendant HRC Medical to remit payment to them of any funds that were not used to pay for actual services rendered.

557. As a result, Defendant HRC Medical has offered consumers "store credit" for the limited number of other products and services it offers, each of which is highly suspect itself. These other products and services include a purported liposuction alternative, a facial peel, a dangerous, non-FDA approved diet involving HCG, and hair restoration therapy.

558. Defendant HRC Medical's no refund policy causes substantial monetary harm, ascertainable losses, and unwarranted health and safety risks to a large number of consumers. The no refund policy encourages consumers to continue with the therapy even if they are experiencing side effects, apply the funds to another questionable medical treatment, or forfeit hundreds or thousands of dollars for BHRT never rendered.

559. Defendant Don Hale and his wife, Dixie Hale, are the only ones at Defendant HRC Medical who have the ability to authorize refunds.

560. Under Defendant Don Hale's instruction, refunds are very rarely given even to those who experience drastic side effects. In one instance, Defendant Don Hale refused to refund a consumer whose wife died (unrelated to BHRT) and was unable to continue with treatments.

561. Defendant Don Hale has denied refunds to consumers after he was notified that they developed breast, cervical, and prostate cancer while or after taking the therapy or experienced drastic side effects during or after taking Defendant HRC Medical's BHRT.

562. This injury is not reasonably avoidable to consumers because of Defendants' deceptive statements about the safety, efficacy, and benefits of Defendant HRC Medical's BHRT; the Defendants' misrepresentations about Defendant Dan Hale's expertise; the complexity of the health effects of hormones for laypeople to understand on their own without medical training; the deference consumers give to doctors and other medical professionals; and the timing that the contract is signed before even blood is drawn and the individual meets with a medical professional. Defendant HRC Medical has also withheld important information about the safety, risks, and benefits of its BHRT.

563. The use of a no refund provision as set forth above has caused or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.

564. Consumers have suffered ascertainable losses as a result of the unlawful acts set forth above in paragraphs 1-563 of this Complaint.

565. All of the advertisements referenced in paragraphs 1-563 of this Complaint were aired, broadcast, appeared, distributed, or otherwise available to consumers in Tennessee.

ADDITIONAL FACTUAL ALLEGATIONS FOR JUDICIAL CORPORATE DISSOLUTION

566. Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1-565 of this Complaint.

567. Employees at Defendant HRC Medical, with management's knowledge and approval, intentionally falsified the medical records of numerous BHRT consumers to make it seem on paper that the hormone pellets were ordered for each consumer at the time the consumer's BHRT hormone pellet dosage decision was made, when this was not the case.

568. As known to Office Manager Dane Hale, one of Don Hale's sons, employees of Defendant HRC Medical would intentionally write the acronym "PO" on numerous medical records of BHRT consumers to indicate "Pellets Ordered," when this was not the case.

569. In reality, the pellets that were used by Defendant HRC Medical for BHRT had been pre-ordered, usually in bulk and were on hand at the office well before a dosage decision for BHRT was made. As one example, Defendant HRC Medical purchased over \$20,000 worth of hormones in advance of ever seeing specific consumers using the "3rd Annual SottoPelle Seminar Special November 2008 Purchase Order Form" from Solutions Pharmacy.

570. Employees of Defendant HRC Medical, with management's knowledge and approval, also used a preprinted list of the same ICD9 codes (standardized diagnosis codes in the medical field) that the company would use for every patient to make it appear on paper as if a doctor had given a particular diagnosis when a doctor had not.

571. Employees of Defendant HRC Medical, with management and Defendant Dan Hale's knowledge, would falsely indicate that doctors at Defendant HRC Medical, including Defendant Dan

Hale and Dr. Charles Emerson, reviewed and approved prescriptions for BHRT and other drugs on pellet ordering forms, prescriptions, and insurance reimbursement forms, when they did not.

572. Unlicensed individuals and registered nurses routinely signed for Defendant Dan Hale, who did not regularly review patient records, to show his approval on paper.

573. In addition, on documents for pellet ordering and insurance forms, a stamp of Dr. Charles Emerson's signature was used to show his approval on paper, even though he largely did not review the forms. The stamp was kept by an unlicensed individual, but was available to everyone who worked at Defendant HRC Medical's Nashville office.

VIOLATIONS OF THE LAW

COUNT I: TENNESSEE CONSUMER PROTECTION ACT Tenn. Code Ann. § 47-18-104(a) and (b)

574. Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1-573 of this Complaint.

575. Defendants' offering of their BHRT, as alleged herein, constitutes "trade," "commerce" and/or a "consumer transaction" as defined in Tenn. Code Ann. § 47-18-103 (19) and as those terms have been interpreted by the Tennessee Supreme Court in *Fayne v. Vincent*, 301 S.W.3d 162, 175 (Tenn. 2009) and elsewhere.

576. By expressly claiming in advertisements for Defendant HRC Medical's BHRT that it is unsafe not to replace one's hormones or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

577. By expressly claiming that Defendant HRC Medical's BHRT is safe, completely safe, absolutely safe, or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant Dan Hale, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

578. By expressly claiming that Defendant HRC Medical's BHRT has no cancer risk or protects against or prevents cancer or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

579. By expressly claiming that Defendant HRC Medical's BHRT has no side effects, limited side effects, or minimal side effects, or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

580. By expressly claiming that Defendant HRC Medical's BHRT does not have the same side effects or risks found in traditional hormone replacement therapy or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Management Midwest, Defendant HRC Medical, Defendant Dan Hale, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), (b)(22), and (b)(27) in each instance.

581. By expressly claiming that Defendant HRC Medical's BHRT can be used to prevent diseases or conditions associated with aging or to increase a recipient's lifespan or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management Midwest and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

582. By expressly claiming that Defendant HRC Medical's BHRT provides cardiovascular benefits, without qualification, or can be used to treat, prevent, or cure cardiovascular problems when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management Midwest, and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

583. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure high cholesterol levels or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

584. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure Alzheimer's Disease or memory loss generally or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management

Midwest, and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

585. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure diabetes or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

586. By expressly claiming, that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure depression or functions as a safer, more effective, or equivalent alternative to prescription anti-depressants or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management Midwest, and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), (b)(22), and (b)(27) in each instance.

587. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure attention deficit hyperactivity disorder or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

588. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure fibromyalgia or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time

made, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

589. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure arthritis or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

590. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure restless leg syndrome or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management Midwest, and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

591. By expressly claiming that Defendant HRC Medical's BHRT can be used to treat, prevent, or cure head hair loss or thinning hair, increases head hair thickness or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical and Defendant Dan Hale, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

592. By expressly claiming that Defendant HRC Medical's BHRT causes weight loss or improves weight control through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management Midwest, Defendant Don Hale, and

Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

593. By expressly claiming that Defendant HRC Medical's BHRT replaces a user's hormones to the levels he or she had in his or her twenties or thirties or in the individual's prime or through words or phrases of similar import, when this is not the case or when this statement was made without adequate support to substantiate such claim at the time made, Defendant HRC Medical, Defendant HRC Management Midwest, Defendant Don Hale, and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(9), (b)(22), and (b)(27) in each instance.

594. By using fabricated quotes from purported studies about the purported benefits, efficacy, risks, and side effects of Defendant HRC Medical's BHRT and by impliedly representing that the quoted purported studies involved non-synthetic hormones, Defendant HRC Medical has violated Tenn. Code Ann. § 47-18-104(a), (b)(3), (b)(5), (b)(22), and (b)(27) in each instance.

595. By claiming that Defendant HRC Medical's BHRT is supported by more studies than it actually is, Defendant HRC Medical and Defendant Dan Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

596. By claiming that Defendant HRC Medical's compounding pharmacy is FDA-approved, has high quality control standards, or produces pellets that are carefully formulated to have a timed release mechanism that optimizes hormone levels, or through words or phrases of similar import, when this is not the case, Defendant HRC Medical and Defendant HRC Management Midwest have violated Tenn. Code Ann. § 47-18-104(a), (b)(3), (b)(5), (b)(22), and (b)(27) in each instance.

597. By claiming that Defendant Dan Hale and other medical staff at Defendant HRC Medical had more expertise with hormones and hormone replacement therapy than they actually did, Defendant Dan Hale, Defendant Don Hale, Defendant HRC Management Midwest, and Defendant HRC Medical have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

598. By claiming that Defendant HRC Medical has more satisfied consumers than it actually does, Defendant HRC Medical, Defendant HRC Management Midwest, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(22), and (b)(27) in each instance.

599. By advertising its BHRT or components of its BHRT without clearly and conspicuously disclosing that Defendant HRC Medical's BHRT increases a user's risk or possible risk of developing serious side effects and health conditions such as endometrial cancer (in women), breast cancer (in women), prostate cancer (men), tissue edema, changes in lipids, blood clots, stroke, heart attack, other cardiovascular problems, hair loss, clitoral swelling (in women), voice changes, testicular atrophy (in men), infertility, female-looking breasts (in men), an inability to produce testosterone naturally (in men), severe acne, hair growth in undesirable areas such as the face, chest, buttocks, arms, and stomach (in women), menstrual or menstrual-like bleeding (in menopausal women), severe acne, severe headaches, and psychological changes such as anger or aggressive behavior, or that the therapy raises testosterone blood levels to male levels in women and significantly above the normal male range in men, Defendant HRC Medical, Defendant HRC Management Midwest, Defendant Dan Hale, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a) and (b)(27), in each instance where Defendant HRC Medical's BHRT was advertised and the clear and conspicuous disclosures were not made.

600. In the limited instances in which side effects of Defendant HRC Medical's BHRT were referenced but did not convey the extent of the side effects accurately or completely, Defendant HRC Management Midwest, Defendant HRC Medical, Defendant Dan Hale, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

601. By using principals, family members, employees, consumers and others with material connections to Defendant HRC Medical, Defendant Don Hale, or Defendant Dan Hale in consumer testimonials in advertisements for Defendant HRC Medical's BHRT without clearly and conspicuously disclosing the ownership interest, family relationship, employment relationship, monetary relationship, compensation, discount on current or future offerings, or other material connections to Defendant HRC Medical or its principals, Defendant HRC Medical, and Defendant Don Hale have violated Tenn. Code Ann. § 47-18-104(a), (b)(2), (b)(3), (b)(22), and (b)(27) in each instance.

602. By using individuals in consumer testimonials who experienced side effects or continuing to run advertisements featuring testimonials from consumers who experienced side effects without clearly and conspicuously disclosing the side effects the consumers experienced, Defendant HRC Medical has violated Tenn. Code Ann. § 47-18-104(a), (b)(22), and (b)(27) in each instance.

603. By representing or implying in consumer testimonials that a consumer took Defendant HRC Medical's BHRT longer than he or she actually did, Defendant HRC Medical has violated Tenn. Code Ann. § 47-18-104(a), (b)(22), and (b)(27).

604. By accepting an advance payment from consumers through cash or financing and using a no refund provision in its contractual documents for Defendant HRC Medical's BHRT for

future medical offerings, without having consumers meet with a medical professional first, without knowing whether Defendant HRC Medical's BHRT will be appropriate, or without knowing how the consumer will respond to the BHRT initially, Defendant HRC Medical and Defendant HRC Management Midwest have violated Tenn. Code Ann. § 47-18-104(a) with each executed contract containing a no refund provision.

605. By actively participating in, approving, directing, or otherwise controlling the acts or practices referenced in paragraphs 1 to 565 on behalf of Defendant HRC Medical Centers, Inc., Defendant Don Hale is individually liable for those acts or practices including those made in bad faith, as they apply to the TCPA violations asserted in paragraphs 574 to 604.

606. By actively participating, approving, directing, or otherwise controlling the acts or practices referenced in paragraphs 1 to 565 on behalf of Defendant HRC Medical Centers, Inc., Defendant Dan Hale is individually liable for those acts or practices, including those made in bad faith, as they apply to the TCPA violations asserted in paragraphs 574 to 604.

COUNT II: JUDICIAL CORPORATE DISSOLUTION

607. Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1-573 of this Complaint.

608. Defendant HRC Medical has carried on, conducted, or transacted its business or affairs in a persistently fraudulent or illegal manner and may be dissolved by judicial decree pursuant to Tenn. Code Ann. § 48-24-304.

PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff, the State of Tennessee, *ex rel.* Robert E. Cooper, Jr., Attorney General and Reporter, pursuant to the Tennessee Consumer Protection Act

of 1977, the Attorney General's general statutory authority, the Attorney General's authority at common law, and this Court's equitable powers, prays:

1. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101 and 47-18-116.

2. That process issue and be served upon the Defendants requiring them to appear and answer this Complaint.

3. That this Court adjudge and decree that Defendants have engaged in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977.

4. That pursuant to Tenn. Code Ann. § 47-18-108(a)(1), (a)(4), and (a)(5), this Court temporarily and permanently enjoin and restrain Defendants from engaging in the aforementioned acts or practices which violate the Tennessee Consumer Protection Act of 1977.

5. That pursuant to Tenn. Code Ann. § 47-18-108(b)(1), this Court make such orders or render such judgments as may be necessary to restore to any person who has suffered any ascertainable loss as defined in Tenn. Code Ann. § 47-18-2102(1) including statutory interest and requiring that Defendants pay all costs of distributing and administering the same, including through the use of a receiver or third-party restitution administrator.

6. Excluding any amounts refunded to consumers, that this Court make such orders or render such judgments as may be necessary to disgorge the profits and ill-gotten gains Defendants realized by reason of the alleged violation of the TCPA.

7. That this Court adjudge and decree that Defendants pay civil penalties of not more than one thousand dollars (\$1,000.00) for each and every violation of the Tennessee Consumer Protection Act of 1977 to the State of Tennessee as provided by Tenn. Code Ann. § 47-18-108(b)(3).

8. That this Court enter judgment against Defendants and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of Defendants' actions, including attorneys' fees and costs, expert and other witness fees, as provided by Tenn. Code Ann. § 47-18-108(a)(5) and (b)(4), and other state law.

9. That all of Defendant HRC Medical's and Defendant HRC Management Midwest's contracts with consumers in Tennessee for BHRT be held void, unenforceable, and uncollectable.

10. That, pursuant to Tenn. Code Ann. § 47-18-108(b)(2), the court permanently revoke Defendant HRC Medical's incorporated status, Defendant HRC Management Midwest's ability to do business as a foreign limited liability company in Tennessee, and revoke Defendant Dan Hale's license to practice medicine as a doctor of osteopathy in the State of Tennessee.

11. That, pursuant to Tenn. Code Ann. § 48-24-301, the court judicially dissolve Defendant HRC Medical as a corporation, issue a decree of dissolution pursuant to Tenn. Code Ann. § 48-24-304(a), and then direct the winding up and liquidation of the corporation's business in accordance with state law.

12. That a receiver be placed temporarily and permanently over Defendant HRC Medical to identify and marshal its assets and liabilities, provide notice to consumers who have purchased Defendant HRC Medical's BHRT, assume legal control over the company, and perform other tasks as set forth in the accompanying motion and proposed receivership order.

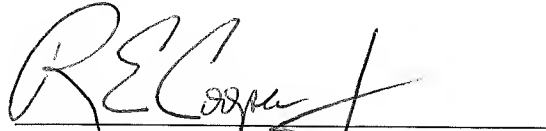
13. That all costs in this case be taxed against Defendants.

14. That a jury be empanelled to hear and decide all appropriate matters.

15. That this Court grant the State such other and further relief as this Court deems just and proper.

This is the first application for extraordinary relief in this case.

Respectfully submitted,



ROBERT E. COOPER, JR.
Attorney General and Reporter
B.P.R. No. 10934



BRANT HARRELL, B.P.R. No. 24470
Assistant Attorney General
CAROLYN U. SMITH, B.P.R. No. 17166
Senior Counsel
Office of the Attorney General of Tennessee
Consumer Advocate and Protection Division
425 Fifth Avenue North, 2nd Floor CHB
Nashville, Tennessee 37243
(615) 741-3549
(615) 532-2910 (fax)
brant.harrell@ag.tn.gov
carolyn.smith@ag.tn.gov